Exhibit A

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION, Plaintiff, v. BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC., Defendants.	Civil Action No. 97-550-SLR (consolidated)
BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC., Plaintiffs, v. ETHICON, INC., CORDIS CORPORATION and JOHNSON & JOHNSON INTERVENTIONAL SYSTEMS CO., Defendants.	Civil Action No. 98-19-SLR
CORDIS CORPORATION, Plaintiff, v. BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC., Defendants.	Civil Action No. 98-197-SLR

JURY VERDICT

We, the jury, unanimously find as follows:

I. INFRINGEMENT

A. DIRECT INFRINGEMENT

1. Do you find that Cordis has shown by a preponderance of the evidence that Boston Scientific's NIR stent literally infringes the following claims? If you answer "YES" as to any claim, proceed to Question 3. If you answer "NO" as to claim 23 of the '762 patent or claim 22 of the '332 patent, proceed to Question 2.

Patent	Claim	YES (for Cordis)	NO (for Boston Scientific)
'762	23*		X

*Depends from claim 13.

Patent	Claim	YES (for Cordis)	NO (for Boston Scientific)
'332	22		X

Patent	Claim	YES (for Cordis)	NO (for Boston Scientific)
'312	21		X

Patent	Claim	YES (for Cordis)	NO (for Boston Scientific)
'370	25*	X	
'370	26	X	

*Depends from claim 22.

2. If you answered "NO" to claim 23 of the '762 patent or claim 22 of the '332 patent in Question 1, do you find that Cordis has shown by a preponderance of the evidence that Boston Scientific's NIR stent infringes under the doctrine of equivalents?

Patent	Claim	YES (for Cordis)	NO (for Boston Scientific)
'762	23	X	

Patent	Claim	YES (for Cordis)	NO (for Boston Scientific)
'332	22		X

3. If you answered "YES" as to any claims in Question 1, do you nevertheless find that Boston Scientific has not infringed the claim or claims to which you answered "YES" because the Reverse Doctrine of Equivalents applies?

Patent	Claim	YES (for Boston Scientific)	NO (for Cordis)
'762	23*		

*Depends from claim 13.

Patent	Claim	YES (for Boston Scientific)	NO (for Cordis)
'332	22		

Patent	Claim	YES (for Boston Scientific)	NO (for Cordis)
'312	21		

Patent	Claim	YES (for Boston Scientific)	NO (for Cordis)
'370	25*	X	
'370	26	X	

*Depends from claim 22.

B. INDIRECT INFRINGEMENT

4. Do you find that Cordis has shown by a preponderance of the evidence that Boston Scientific has contributorily infringed claim 44 of the '762 patent?

Patent	Claim	YES (for Cordis)	NO (for Boston Scientific)
'762	44	X	

II. VALIDITY

A. '762 PATENT

5. Do you find that Boston Scientific has shown by clear and convincing evidence that the subject matter of claim 44 of the '762 patent fails to comply with 35 U.S.C. § 305?

YES (for Boston Scientific)	NO (for Cordis)
X	

B. '332 PATENT

6. Do you find that Boston Scientific has shown by clear and convincing evidence that the subject matter of claim 22 of the '332 patent would have been obvious from the prior art to a person of ordinary skill in the art?

YES (for Boston Scientific)	NO (for Cordis)
X	

7. Do you find that Boston Scientific has shown by clear and convincing evidence that claim 22 of the '332 patent fails to comply with the written description requirement of 35 U.S.C. § 112?

YES (for Boston Scientific)	NO (for Cordis)
	X

C. '312 PATENT

8. Do you find that Boston Scientific has shown by clear and convincing evidence that the subject matter of claim 21 of the '312 patent would have been obvious from the prior art to a person of ordinary skill in the art?

YES (for Boston Scientific)	NO (for Cordis)
	X

9. Do you find that Boston Scientific has shown by clear and convincing evidence that claim 21 of the '312 patent fails to comply with the written description requirement of 35 U.S.C. § 112?

YES (for Boston Scientific)	NO (for Cordis)
	X

D. '370 PATENT

10. Do you find that Boston Scientific has shown by clear and convincing evidence that claim 25 of the '370 patent fails to comply with the written description requirement of 35 U.S.C. § 112?

YES (for Boston Scientific)	NO (for Cordis)
	X

11. Do you find that Boston Scientific has shown by clear and convincing evidence that claim 26 of the '370 patent fails to comply with the written description requirement of 35 U.S.C. § 112?

YES (for Boston Scientific)	NO (for Cordis)
X	

Each juror should sign the verdict form to reflect that a unanimous verdict has been reached.

Dated: December 11, 2000

FOREPERSON

Exhibit B

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION, Plaintiff, v. BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC. Defendant.	)	Civ. No. 97-550-SLR (Consolidated)
BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC., Plaintiffs, v. ETHICON, INC., CORDIS CORPORATION and JOHNSON & JOHNSON INTERVENTIONAL SYSTEMS COMPANY, Defendants.	)	Civ. No. 98-019-SLR

SPECIAL VERDICT FORM

We, the jury, unanimously find as follows:

Infringement

Has Cordis shown by a preponderance of the evidence that Boston Scientific's NIR stent infringes the limitation of claim 23 of the '762 patent requiring that the wall of a tubular member have a substantially uniform thickness? (A "YES" answer to this question is a finding for Cordis. A "NO" answer is a finding for Boston Scientific.)

YES ✓ NO ____

Invalidity

Do you find that Boston Scientific has shown by clear and convincing evidence that claim 23 of the '762 patent is invalid due to obviousness? (A "YES" answer is a finding for Boston Scientific. A "NO" answer is a finding for Cordis.)

YES ____ NO ✓

You must sign this Verdict Form.

Dated: March 24 , 2005

Raymond M. Martin
FOREPERSON

Angela Crapper

Joan E. Sloan

Mary Mazzetti

Dirk G. Gleysteen

Paul Ouellette

Stefan Wooters

Exhibit C

United States Patent

Ersek

[15] **3,657,744**

[45] **Apr. 25, 1972**

[54] METHOD FOR FIXING PROSTHETIC IMPLANTS IN A LIVING BODY

[72] Inventor: **Robert A. Ersek**, St. Louis Park, Minn.

[73] Assignee: **The Regents of the University of Minnesota**, Minneapolis, Minn.

[22] Filed: **May 8, 1970**

[21] Appl. No.: **35,815**

[52] **U.S. Cl.**.....**3/1**, 3/DIG. 1, 3/DIG. 3, 128/334 R

[51] **Int. Cl.**.....**A61f 1/22**, A61f 1/24

[58] **Field of Search**.....128/334 R, 334 C, 341, 343, 128/348; 3/1, DIG. 1, DIG. 3

[56] **References Cited**

UNITED STATES PATENTS

3,509,883	5/1970	Dibelius	128/348
3,221,746	12/1965	Noble	128/334 R

FOREIGN PATENTS OR APPLICATIONS

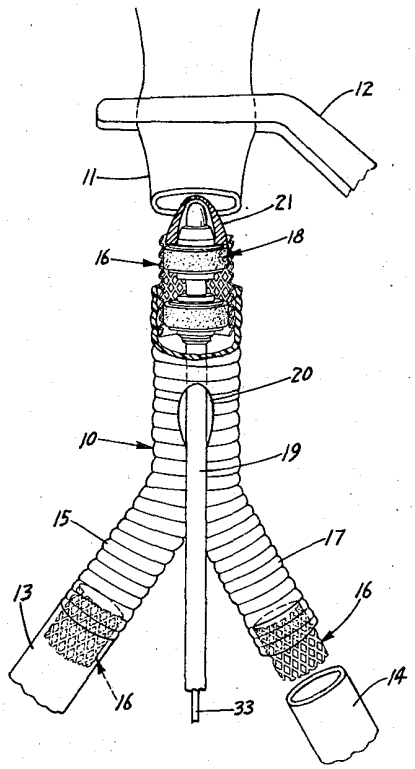
180,750	9/1966	U.S.S.R.	3/DIG. 3

Primary Examiner—Richard A. Gaudet
Assistant Examiner—Ronald L. Frinks
Attorney—Burd, Braddock & Bartz

[57] **ABSTRACT**

A device and method for facilitating the rapid positive fixation of implanted prosthetic members in a living body. The device comprises a tubular sleeve of deformable material to which the prosthetic member is secured and which is capable of being expanded radially into intimate engagement with surrounding tissue. The fixation device and prosthetic member, such as heart valve, vessel graft, etc., are prepared by assembly prior to surgery. The assembly may be rapidly introduced into the transplant situs during surgery and secured in place by expansion of the deformable sleeve by use of an expansion tool.

3 Claims, 9 Drawing Figures



PATENTED APR 25 1972 3,657,744

SHEET 1 OF 2

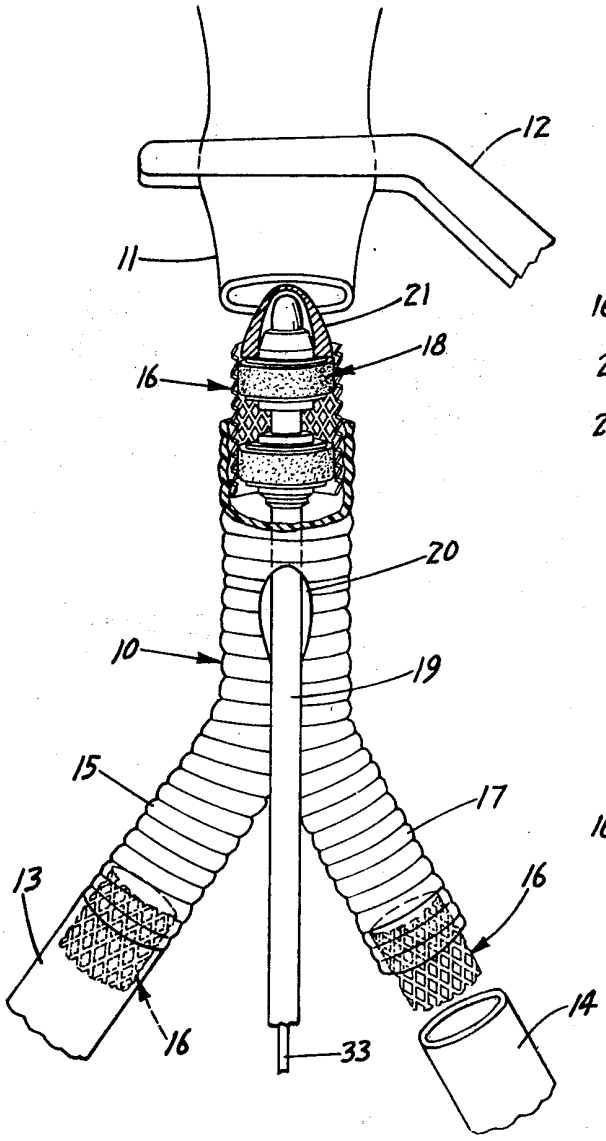


FIG. 1

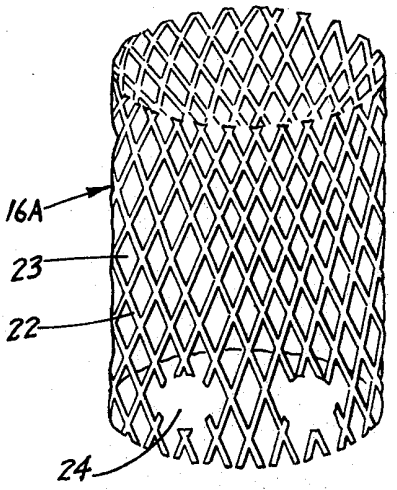


FIG. 2

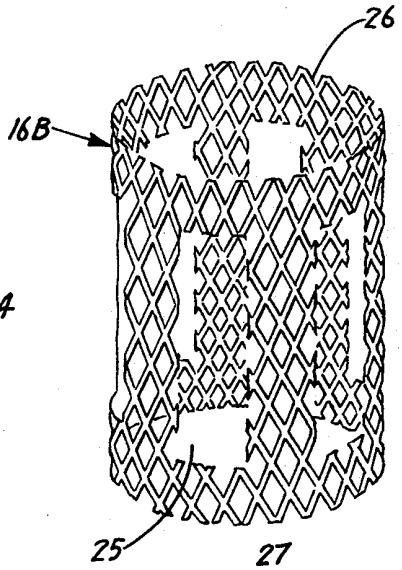


FIG. 3

INVENTOR.
ROBERT A. ERSEK

Burd, Braddock & Bartz

ATTORNEYS

PATENTED APR 25 1972 3,657,744

SHEET 2 OF 2

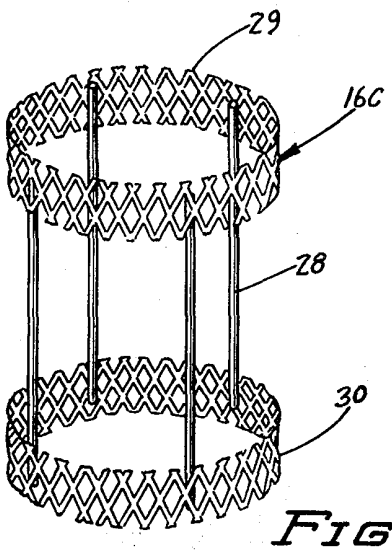


FIG. 4

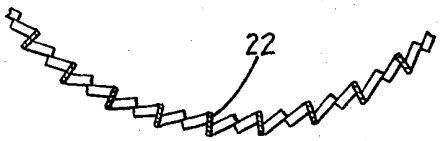


FIG. 5

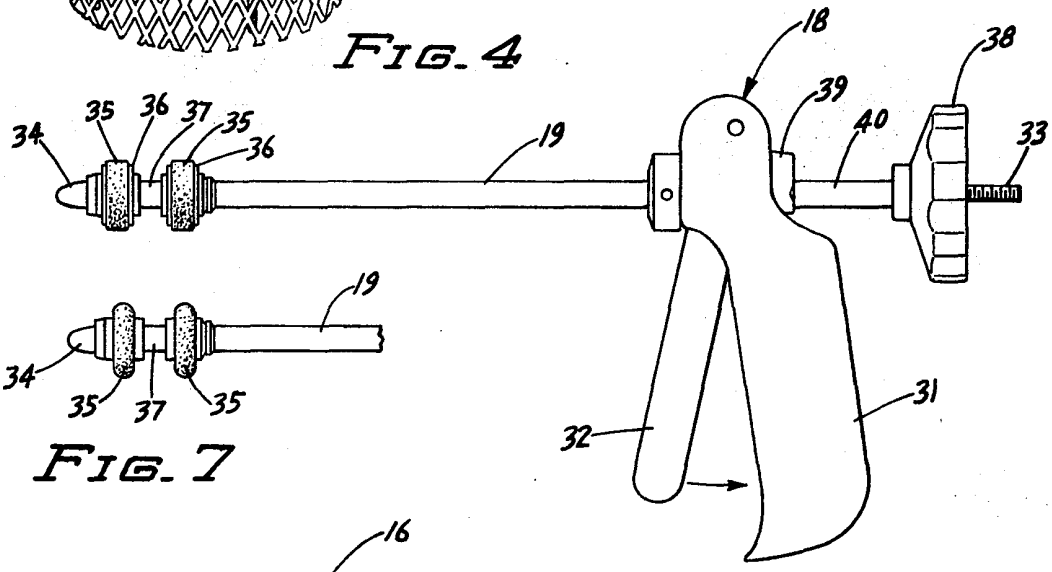


FIG. 7

FIG. 6

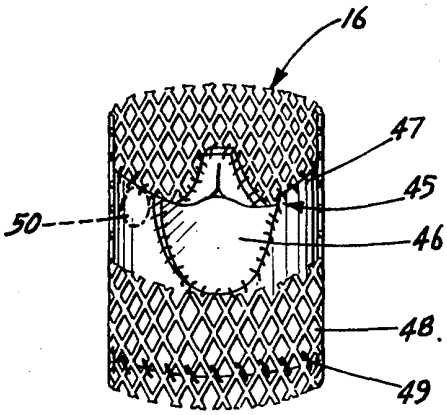


FIG. 8

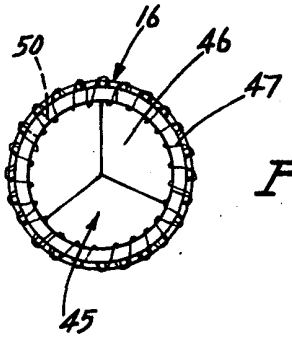


FIG. 9

INVENTOR.
ROBERT A. ERSEK
BY
Burd, Braddock & Bartz
ATTORNEYS

METHOD FOR FIXING PROSTHETIC IMPLANTS IN A LIVING BODY

This invention relates to a device and method for the rapid positive fixation of implanted prosthetic members in a living being. Many thousands of implants of prosthetic members, either artificial members or homografts or grafts from other animal species are made annually. Vessel grafts and heart valve implants are becoming commonplace. Transplantation of large organs such as the heart, lungs, liver, etc. is taking place in ever increasing numbers.

The fixation device according to the present invention comprises a tubular sleeve of deformable material to which the prosthetic member is secured and which is capable of being expanded radially into intimate engagement with the tissue surrounding the implant situs. It has been found through animal experimentation that the implant may be made rapidly and positively, without fear of dislodgment or leakage. When formed of a compatible material, the fixation device is well tolerated by the body and becomes completely covered by tissue leaving no exposed surface for the formation of clots and thrombi.

According to the prior art, artificial heart valves are installed by the careful placing of a plurality of stitches around the rim of tissue that will house the valve. These stitches are passed through a suture ring around the outside of the heart valve. The valve to be implanted is held outside of the heart 6 or 8 inches and each stitch is brought up through the suture ring while the valve is still so held. When the sewing is finished, the valve stands some distance above the heart and has 20 or 30 sutures going down to the tissue where it will finally rest. The sutures are held tight and the heart valve is slid down them into place and each suture is then individually tied. This process takes 30 to 45 minutes in the best hands and from an hour to an hour and one-half in the less then best.

In the case of the transplantation of a graft valve from another patient or from an animal, sewing takes more than an hour. Although excellent results have been reported with these transplanted valves, few surgeons are using them today because of the great time that must be taken to sew them in. Valve installation takes place while the patient is on an artificial heart-lung machine and every minute is very important.

One form of prior art heart valve is available wherein a caged ball valve is provided in its outer rim with a plurality of radially extending teeth which by screw means are caused to engage the aortic wall. Such valves, though expensive, are satisfactory where there is a very tight initial fit and where the aortic wall is of uniform consistency and size, conditions which cannot always be depended upon to exist. Accordingly, problems have arisen relating to aortic incompetence due to blood flow working its way between the prosthesis and the aortic wall in the many instances where no positive fixation is achieved by the tooth members.

The device of the present invention permits instant and positive fixation of heart valves, vessel grafts and other prosthetic members. The valve or other prosthetic member is prepared for implantation by attachment to the openwork sleeve. The valve and its skirt composed of the sleeve is assembled on an expanding tool device. This assembly can be quickly and easily forced into place and the tubular sleeve expanded to hold the valve or other member in place. This is done in a small fraction of the time required for other transplants so that in many instances use of the heart-lung machine is not required. The fixation sleeve expands so that a snug fit is assured regardless of the size, shape or consistency of the tissue wall at the implantation situs. Since the sleeve becomes incorporated into the tissue wall, no foreign material is left in contact with the blood, as opposed to prior art devices.

The invention is illustrated by the accompanying drawings in which:

FIG. 1 is a schematic view showing three stages of the grafting of an artificial bifurcation vessel graft utilizing the fixation device according to the present invention;

FIG. 2 is a perspective schematic view of one modified form of prosthetic fixation device;

FIG. 3 is a perspective view of another modification;

FIG. 4 is a perspective view of a further modification;

FIG. 5 is a schematic representation of a portion of the perimeter of any one of the devices of the preceding FIGS., as seen in transverse section;

FIG. 6 is an elevation of one form of expanding tool which may be utilized with the fixation device;

FIG. 7 is a fragmentary elevation of the operating end of the expanding tool showing the tool in expanded condition;

FIG. 8 is a perspective elevational view with the upper half of the fixation device in section, and showing the fixation device with a heart valve attached for implantation; and

FIG. 9 is a top plan view of the assembly of FIG. 8.

Referring to the drawings, and particularly to FIG. 1, there is shown schematically one manner in which the prosthesis fixation device according to the present invention is used. This use is illustrated with respect to the implantation of an artificial bifurcated aortic Dacron graft, indicated generally at **10**, between the severed aorta **11**, shown with a Satinsky clamp preventing flow, and the common iliac arteries **13** and **14**. A completed joint is shown between the artery **13** and one branch **15** of the artificial vessel transplant. The ends of the artery and prosthesis are in butting relation held by an expanded fixation sleeve, indicated generally at **16**, within the host-prosthesis junction. A similar sleeve **16** is shown partially within the branch **17** of the prosthesis **10** about to be connected to the artery **14**.

The manner in which the junction is made is shown with respect to the severed end of the aorta **11**. An expandable sleeve fixation device **16** is shown extending from the end of the artificial vessel graft **10** with about half of its length engaging the inside wall of the graft. The head of an expander tool, indicated generally at **18**, whose tubular barrel **19** extends through a slit **20** in the graft, is positioned within the sleeve. A tapered tip **21** placed on the end of the expanding tool facilitates entry of the assembled graft, tool and fixation device **16** into the aorta. When in place, with the ends of aorta **11** and graft **10** butting, the sleeve is expanded by operation of the expanding tool to force the fenestrations of the sleeve into the wall of the aorta to achieve a leak-proof union and forcing the walls of the sleeve into tighter engagement with the inside wall of the graft **10**.

After the sleeve is expanded, the tool is withdrawn. A smaller headed tool is inserted through slit **20** from the opposite direction to within the fixation device **16** of lesser diameter for connection with artery **14**. The exposed end of sleeve **16** is inserted into the lumen of the artery **14** and the sleeve is expanded to make the joint. The tool is withdrawn, slit **20** is clamped shut and clamp **12** is removed to permit resumption of blood flow. The entire transplant can be made in a matter of a very few minutes to the point of restoration of the blood supply. The longitudinal slit in the graft may then be sewn closed at leisure in confidence that the blood is being supplied distal to the graft site.

The tubular sleeve **16** is made of deformable material such that it retains its expanded dimensions after expansion in place. It is formed from a non-toxic material compatible with blood and other body fluids, such as stainless steel. Its walls desirably have a large percentage of open area so as to permit proliferation of the intima of the vessels through the openings and over the intervening strand-like or ribbon-like members. Preferably the openwork sleeve is formed from so-called "expanded metal" sheeting which is produced by forming a series of staggered parallel slits in an impervious metal sheet and then stretching the sheet in a direction perpendicular to the slits to open the slits into apertures and expand the metal sheet in that direction while contracting it slightly in the opposite direction. The stretching operation by which the metal sheet is expanded imparts a twist or bend to the undulating flat ribbon-like portions **22** of the metal sheet separating the diamond-shaped apertures **23** which are generally uniformly sized and distributed. This twisting or bending of the metal members **22** between adjacent apertures imparts an angle or direction to the apertures themselves and to the ribbon-like members.

The expanded metal sheeting is desirably not flattened prior to forming into a sleeve. The result, as seen schematically in FIG. 5, is that the ribbon-like portions 22 of the sleeve extend angularly relative to the perimeter of the sleeve providing a multitude of narrow projecting edges which embed themselves into the tissue wall upon expansion of the sleeve. After being formed with the members 22 extending generally longitudinally, the sleeve is desirably spot welded to form a longitudinal seam. The tubular sleeve may be circular, oval, or polygonal (hexagonal, octagonal or the like) in cross-section. The cross-sectional area may be uniform along the length of the sleeve or it may vary, giving the sleeve generally a barrel shape or that of a truncated cone. The edges may be cuffed if desired or simply smoothed to facilitate entry. The sleeve may easily be expanded by about 50 percent beyond its original diameter. The sleeves are formed to be a size appropriate for the implant being made. The strands 22 and apertures 23 are sized proportionately.

Because of the twisted relation of the ribbon-like portions of the sleeve, protrusion of the vessel lining is facilitated with the result that very little metal is actually in contact with the blood stream. Experimentally it has been determined that within a few seconds a fine clot layer is laid down over the stainless steel struts forming a physiological bridge from the islands of intima where the vessel lining protrudes through the apertures in the sleeve.

Instead of metal, the tubular fixation sleeve may be formed from other natural or synthetic materials having the requisite properties and characteristics permitting the sleeve to be expanded into secure attachment with surrounding tissue. Desirably the material is one which is capable of being absorbed over an extended period of time by the tissue to which the sleeve is attached. A number of such absorbable materials are known.

In the form of fixation device shown in FIG. 2, sleeve 16A is provided with a plurality of circular holes 24 (which are of larger area than apertures 23) punched through the openwork wall around the sleeve adjacent one end to allow for the ostia of the coronary arteries.

In FIG. 3, a modified form of sleeve 16B is provided with a plurality of relatively large rectangular openings 25 extending longitudinally to permit exposure of wide areas around the coronary artery ostia. This form of fixation device is intended for the implantation of heart valves. The valve is hung with its commissures secured along the upper and lower ring portions 26 and 27, respectively, whose widths are about one-eighth to one-fourth the length of the sleeve.

In FIG. 4, the fixation device includes a plurality of longitudinal wire struts 28 separating two expandable and relatively narrow metal mesh ring sections 29 and 30. A three-pronged commissure valve is inserted in the upper expandable ring section 29 and secured to the bottom mesh ring 30 circumferentially.

A variety of expanding devices may be used to set the fixation devices in place. One form of such tool is shown in FIG. 6. The device includes a pistol-grip handle 31 and a trigger-like operating lever 32 pivoted therein. An elongated tubular barrel 19 extends out from the handle means. A concentric rod 33 extends through the handle 31 and barrel 19 terminating in a fitting 34 beyond the muzzle end of barrel 19 at its forward tip. Expansion means, comprised of a pair of resilient rings 35, each held between a pair of washers 36 and held spaced apart by a rigid spacer ring 37, are disposed between the muzzle end of barrel 19 and tip fitting 33. Operation of the lever 32 by gripping and squeezing to move it toward the handle causes rod 33 to shorten its exposed length in relation to barrel 19 such that squeezing force causes the resilient rings to decrease their longitudinal dimensions. Being non-compressible, they expand radially outwardly increasing their lateral dimensions, as shown in FIG. 7. In this way, a predictable dependable amount of expansion can be achieved. The breech end of rod 33 is threaded and fitted with a knurled knob 38. The heel 39 of operating lever 32 bearing against a spacer tube 40, which in turn bears against knob 38, causes the relative movement between barrel 19 and rod 33. Alternatively, force may be exerted simply by rotation of knob 38 and adjustment of the at-rest force exerted upon the expansion rings may be made. One, two or more expandable rings 35 may be used. The pattern of expansion can be predetermined as desired by selection of appropriate spacing between those rings.

When used for the installation of artificial vessel grafts made of Dacron, Teflon or similar artificial materials, the fixation sleeve is attached to the vessel graft some time prior to surgery and a longitudinal slit is made in the middle of the graft for the introduction of the expansion tool. At the time of surgery, the ends of the vessel to be grafted are secured through simple stay stitches or small clamps so that the fixation sleeve can be introduced thereto. The expander tool is in place in one of the sleeves at the time of introduction. This sleeve is then expanded in situ and the expander tool is removed through the longitudinal slit, turned around and used to expand the fixation sleeve at the other end and again removed. The longitudinal slit is clamped and the clamps or stitches securing the vessels to be grafted are removed to restore the blood flow. Very rapid fixation of vessel grafts is thus possible.

In FIG. 8 there is shown an aortic heart valve 45 in place in a fixation sleeve 16. The rim of valve 45 adjacent the cusps 46 is attached by sutures 47 to the sleeve near one end. A segment of the donor aorta 48 is attached by sutures 49 near the other end of sleeve 16. The opening 50 in the aorta wall for a coronary artery can be matched with the corresponding opening in the wall of the donee aorta.

When used for the fixation of heart valves, whether a transplant or artificial, the valve is secured within the fixation sleeve prior to surgery and the sleeve is assembled in the expansion tool. Then, at the time of surgery, the sleeve is rapidly expanded into place and the tool withdrawn. When used for implantation of heart valves in the aortic position, a total introduction time of only a few minutes is necessary. This means that an aortic valve may be placed without use of a heart-lung machine. Inflow of blood into the heart is occluded by placing clamps across the appropriate vessels. A longitudinal slit (aortotomy) is placed in the aorta just a few centimeters above where it begins. This slit is opened and the existing defective valve is removed. The new valve housed in the expandable sleeve is then placed in position and the sleeve is expanded in one stroke of the expanding tool. The expansion tool is then removed through the aortic slit and a clamp placed over it, thus allowing the restoration of blood flow so that only a few minutes total introduction time is required. The aortotomy can then be repaired at leisure after the heart has taken over its pumping function.

It is apparent that many modifications and variations of this invention as hereinbefore set forth may be made without departing from the spirit and scope thereof. The specific embodiments described are given by way of example only and the invention is limited only by the terms of the appended claims.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A method for rapidly and positively fixing an inplanted prosthetic device in a living body which comprises:

A. securing the prosthetic device to be implanted to at least one openwork tubular sleeve of non-toxic deformable material compatible with body fluids and capable of being expanded radially, said sleeve being of a diameter corresponding to the prosthetic member to be implanted and adapted for attachment to the prosthetic member, and including a plurality of longitudinally extending ribbon-like undulating portions disposed angularly with respect to the perimeter of said sleeve and interconnected to define a plurality of staggered closely spaced apertures,

B. introducing the sleeve and prosthetic device into a prepared transplant situs, and

C. expanding the sleeve radially outwardly against the tissue walls of said situs and forcing the undulating ribbon-like

portions of the sleeve into intimate engagement therewith, whereby the tissue may grow through and around the sleeve to cover the same.

2. A method according to claim 1 further characterized in that:

A. said prosthetic device to be implanted is a vessel graft,

B. said openwork sleeve is inserted partially and secured in each end of said vessel graft leaving an exposed portion of sleeve extending therefrom,

C. said graft is provided with a longitudinal opening to receive a sleeve expanding tool;

D. said prosthetic device and sleeves are joined to the host vessels to be grafted by introduction of the exposed portions of said sleeves into the severed host vessels, and

E. the sleeves are expanded radially outwardly into intimate engagement with the walls of said vessels and said graft.

3. A method according to claim 1 further characterized in that:

A. said prosthetic device to be implanted is a heart valve,

B. said valve is secured within one end of said sleeve,

C. said sleeve and valve are introduced into the situs of the defective valve to be replaced, and

D. said sleeve is expanded into engagement with the surrounding tissue.

* * * * *

Exhibit D

3:01 P.M.

993. Expandable Intraluminal Graft: A Preliminary Study

Julio C. Palmaz, M.D., San Antonio, TX, Randy R. Sibbitt, M.D., Stewart R. Reuter, M.D., J.D., Fermin O. Tio, M.D., William J. Rice, M.D.

In an attempt to overcome the problem of restenosis after vascular balloon dilatations, we have developed an expandable intraluminal graft that allows dilatation of the lesion and simultaneous placement of a supportive endoprosthesis to prevent recoil of the arterial wall. The graft is made of continuous, woven, stainless steel wire with soldered cross points. The resulting tubular mesh has a wall thickness of 20–45 microns and a 98% open surface. Eleven grafts of six, eight, and 10 ml in diameter by 20 ml in length were placed in the aorta, common carotid, superior mesenteric, iliac, and renal arteries of dogs. Six grafts showed no stenosis in follow-up studies up to 8.5 weeks. Two grafts had moderate stenosis as a result of neointimal hyperplasia. Two partial and one complete graft thrombosis occurred in nonheparinized animals in which the graft outflow was restricted. No long-term anticoagulation was used. Light and electron microscopy studies showed complete endothelization of the inner surface of the graft at three weeks.

Radiology

NOVEMBER/1984 Volume 153 (P) Special Edition

Head and Neck Radiology · Nuclear Medicine · Diagnostic Radiology · Computed Tomography · Radiation Physics · Interventional Radiology ·

70TH Scientific Assembly and Annual Meeting

Washington, D.C./November 25–30, 1984

Magnetic Resonance · Pediatric Radiology · Ultrasound · Radiation Biology · Therapeutic Radiology · Neuroradiology

including sessions in joint sponsorship with the American Association of Physicists in Medicine

SCIENTIFIC PROGRAM

Works in Progress—General Diagnosis

Thursday Afternoon —Nov. 29, 1984 2:45-3:45 P.M.
Computer Code: U16 Credits: 1 hour

Room 36

Barry D. Toomba, M.D., Houston, TX, Presiding

2:45 P.M.

991. Angioscopy: Application in Arterial Occulsive Disease

Amir Motarjeme, M.D., Chicago, IL, Bruno Cortis, M.D.

The nature of occlusion has a great significance in management of arterial occlusive disease. Not infrequently, angiography alone is unable to differentiate between atherosclerotic and thromboembolic arterial occlusive disease. With percutaneous transluminal angioplasty being accepted as an alternate to surgery in management of atherosclerotic occlusive disease, it is essential to be able to differentiate between arterial occlusions due to atherosclerosis and thromboembolic disease. With commercially available small caliber angioscopes (4–8 F) it is now possible to look at the arterial occlusive lesions directly to arrive at a correct diagnosis. We report on our limited experience in angioscopy both prior to and after percutaneous transluminal angioplasty to evaluate the nature of occlusion and also to observe the result of PTA.

2:53 P.M.

992. Mediastinal Lymphography Using Water Soluble Contrast Medium

Taneyasu Tauchi, M.D., Nagoya City, Japan, Michio Kono, M.D., Hirochika Suzuki, M.D., Kenji Kurono, M.D., Eriko Okumura, M.D., Michimasa Maisuo, M.D.

In cases of lung cancer, the diagnosis of lymphnodal metastasis is very important, before surgery or conservative therapy is started. Some diagnostic modalities, such as CT, bronchial arteriography, and radionuclide studies, are available for this purpose; however, these studies do not always supply accurate information. Some clinical trials of mediastinal lymphography using oily contrast medium have been carried out, but practical applications of these agents have been limited. According to our preliminary data derived from canine experiments, contrast medium of low viscosity and low permeability was well adapted for mediastinal lymphography. Based on this result, we performed mediastinal lymphography in a clinical setting using metrizamide—a nonionic and water-soluble contrast medium. In 23 cases of lung cancer, mediastinal lymphography was performed at thoracotomy. Five to 10 ml of metrizamide was injected directly into mediastinal lymph nodes. The mediastinal lymphographic findings correlated well with histological findings. A trial of mediastinal lymphography with transbronchial injection of metrizamide bronchoscopically was performed, and the results will be reported.

3:01 P.M.

993. Expandable Intraluminal Graft: A Preliminary Study

Julio C. Palmaz, M.D., San Antonio, TX, Randy R. Sibbitt, M.D., Stewart R. Reuter, M.D., J.D., Fermin O. Tio, M.D., William J. Rice, M.D.

In an attempt to overcome the problem of restenosis after vascular balloon dilatations, we have developed an expandable intraluminal graft that allows dilatation of the lesion and simultaneous placement of a supportive endoprosthesis to prevent recoil of the arterial wall. The graft is made of continuous, woven, stainless steel wire with soldered cross points. The resulting tubular mesh has a wall thickness of 20–45 microns and a 98% open surface. Eleven grafts of six, eight, and 10 ml in diameter by 20 ml in length were placed in the aorta, common carotid, superior mesenteric, iliac, and renal arteries of dogs. Six grafts showed no stenosis in follow-up studies up to 8.5 weeks. Two grafts had moderate stenosis as a result of neointimal hyperplasia. Two partial and one complete graft thrombosis occurred in nonheparinized animals in which the graft outflow was restricted. No long-term anticoagulation was used. Light and electron microscopy studies showed complete endothelialization of the inner surface of the graft at three weeks.

3:09 P.M.

994. Experimental Results with a New Vena Caval Filter

Rolf W. Günther, M.D., Mainz, West Germany, Hans Schild, M.D., S. Storkel, M.D., A. Fries

A new inferior vena cava filter device was studied in 24 dogs. The filter consists of a steel wire basket and several struts. It can be introduced percutaneously through a 10-F Teflon catheter under fluoroscopic control. The construction of the filter allows antegrade and retrograde placement and extraction in case of malposition. Due to the firm attachement of the device to the intimal surface and fibrotic encasement of the wires in the vessel wall, displacement and tilting of the filter are avoided. *In vivo* and *in vitro* studies demonstrated the capability of the filter to entrap emboli as small as 15×2 mm in 90% of cases; all larger emboli were trapped. Long-term thrombogenicity studies 3–4 months after filter insertion showed patency of the inferior vena cava in six dogs.

3:17 P.M.

995. Fibrinolytic Therapy by Means of Intrathrombotic Injections of Streptokinase: Technique and Clinical Experience in Chronic Arterial Occulsion

Johannes Lammer, M.D., Graz, Austria, Ernst Pilger, M.D., Erwin Jusich, M.D., Klaus Neumeyer, M.D., Heribert Schreyer, M.D.

Local fibrinolytic therapy of chronic arteriosclerotic obstructions by means of intrarterial infusion of streptokinase had a success rate of only 50% or less. Due to collateral vessels originating proximal to the tip of the thrombus, only minimal doses of infused streptokinase come in contact with the thrombus. Therefore, a technique was developed to infiltrate the thrombus with streptokinase from inside by means of intrathrombotic injections. The tip of the endhole catheter had to be within the thrombus during the entire procedure. Two thousand five hundred units of streptokinase were injected every five minutes. Every 15 minutes the catheter was advanced within the thrombus. In long stenoses 2,500–5,000 units of heparin were administered to avoid rethrombosis of the proximal segment. The recanalization was completed by angioplasty. Forty-seven patients with iliac or femoropopliteal obstructions of more than six weeks duration (up to one year, mean four months) and a length of 10–65 cm (mean 22 cm) were included in this study. The primary recanalization rate was 75%; the patency rate after two weeks was 68%. Failure of recanalization was most commonly caused by subintimal dissection. The procedure took 1–7 hours (mean 2.5 hours), and the total dose of streptokinase was 30,000–185,000 units (mean 70,000 units).

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Historical Review:

In January 1964, Dotter performed the first successful percutaneous transluminal angioplasty (PTA) using progressive luminal dilatation by means of a system of coaxial catheters (1). The method had little acceptance in the U.S. but gained interest among several investigators in Europe. At an international congress devoted to PTA 1800 cases were presented from twelve groups of authors. Portsman (2) first reported, in 1973, the use of a balloon catheter to dilate arterial stenosis. A modified version of this balloon, the so-called caged balloon, was described by Dotter and manufactured by Cook, Inc., Bloomington, Indiana. 47 401. Gruntzdig and Hopff (3) introduced an angioplasty balloon catheter able to accept relatively high pressures without loosing the balloon shape. The balloon is made of polyvinyl chloride and is smoothly tapered at both ends.

Technique and Applications:

Gruntzdig balloon catheters are manufactured in several balloon lengths and diameters (4). Effective dilatation pressure varies between 3-5 atm P, and can be obtained with single 2 cc plastic syringe using diluted contrast material or with specially manufactured pumps which deliver measured amounts of CO_2 under positive and negative pressures for quick inflation and deflation. Total obstructions may be recanalized by first traversing the lesion carefully with a "J" tip teflon coated movable core guide wire. Some authors recommend the use of Aspirin or Persantine 48 or 72 hours prior to PTA. Once the catheter is in place 5000 IU of heparine are injected in the arterial lumen. In addition Gruntzdig recommends the IA injection of Priscoline

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or ATP prior to PTA to increase peripheral flow. The balloon is expanded up to four times as needed, during 30 to 60 seconds. Contrast injections are made between dilatations to evaluate the results under fluoroscopy. Pressures are recorded proximal and distal to the stenosis in iliac and superficial femoral dilatations. In femoral and popliteal lesions the flow changes are better monitored by Doppler measurements. (5)

The prime indication for dilatation is a relatively short segment of stenosis in a medium size artery (6). Both the axillary and femoral approaches are feasible. Renal, (7,8) coronary and vertibral artery stenoses have been treated successfully. Total occlusion recanalization is attempted in the superficial femoral artery if the occluded segment is 10 cm or shorter (1,4). No recanalization should be attempted in iliac obstructions because in case of perforation of the vessel wall the ensuing hemorrhage is defficult to control (4).

Contraindications to PTA (6) are a) stenosis at the point of origin of an essential or principal collateral. b) Segment of occlusion larger than 10 cm, c) Intraluminal calcification. d) Multiple stenosis of the superficial and deep femoral arteries without an elaborate collateral system. e) stenosis at a single remaining artery below the knee. Combined PTA with surgical treatment is indicated in patients with localized iliac stenosis and obstruction of long segments of superficial femoral artery. The dilatation of the proximal lesion would support the effectiveness of a femoropopliteal bypass (6).

Reported Results:

Dotter estimates that over 15,000 percutaneous transluminal angioplasties have been performed so far. (9) The same author considers that in about 80-90% of properly selected cases there is immediate relief after a procedure which entails no more risk than the angiographic study usually required prior to surgery. Gruntzdig has treated over 300 patients since 1971 (4). He had an initial success rate of 84% for recanalization of femoro-popliteal occlusions and 92% for iliac artery stenosis. In his hands the two year patency rate is 72% for successfully treated femoropopliteal lesions and 87% for iliac artery stenosis.

Complications inherent to the procedure include subintimal hemorrhage and thrombosis, distal embolization and rupture of the wall. Circumferential balloon tears may prevent withdrawal of the catheter and require surgery.

Failure in performing successful dilatation happens in 10-20% of the times. Failure is not considered a complication by most authors, provided that there is not a post-procedure change that makes the patient's circulatory status worse. Nevertheless, this criterion must be used rather flexibly by some authors in view of the low complication rate reported. The complication rate varies from 5 to 7% (4,5) . For some investigators small distal embolization is insignificant if it is not clinically apparent. (10).

Histopathologic Changes in PTA:

Since the introduction of the method by Dotter and Judkins (1), the basic mechanism of angioplasty has been thought to be compression and redistribution of the atheromatous material against the vessel wall. Recently Castaneda-Zuniga, et al (11) have demonstrated that the atheromatous material is incompressible and that the increase in the arterial lumen obtained by PTA is due to stretching of the arterial wall. Microscopic examination of dilated arteries showed fragmented intima and compaction and stretching of elastic fibers with loss of undulation. The nuclei of the smooth muscle cells adopt a peculiar corkscrew appearance. By dilating isolated arteries of cadavers these authors observed that the vessels stretched and then resumed their original size as soon as the balloon was deflated, probably due to lack of blood pressure. Nevertheless, beyond certain degree of circumferential widening the arterial wall stretching was irreversible. The non-elastic atheromatous material undergoes fissuring and separation from the stretched elastic base being therefore prone to become dislodged. Further stretching of the vessel wall results in rupture of all layers.

On the basis of the explained mechanism the balloon has to produce enough circumferential dilatation as to surpass the elastic property of the vessel wall producing an aneurysmal deformity to accomodate the fractured atheromatous material so as to maintain a lumen uniform with the adjacent normal artery. Although the practice has proven that 3-5 atm P is adequate to obtain satisfactory dilatation it is not difficult to conceive that it would not be possible to safely establish which pressure

is adequate to each case. If the pressure is too low, no change is produced. If the pressure is too high distension of the vessel wall may reach the point of rupture. The limits between these two extremes may be rather narrow in certain situations of severe degenerative changes and calcification.

Proposed alternative to balloon dilatation:

The fractured atheromatous material may be contained against the vessel wall by placing an intraluminal tubular structure which may be expanded at one time with the stenotic lesion. The tube should be mounted on the balloon and introduced in the artery with it. Once it is in place the balloon insuflation would expand the tube and the stenotic lesion together. The tube should have memory properties so as to oppose the elastic recoil of the wall. The tube would at the same time, maintain the lumen, avoid dislodgment of atheromatous material and give structural support to the wall. Theoretical drawbacks include:

a) Reduction of the longitudinal flexibility of the artery.

b) Thrombogenicity of the prosthetic material.

c) Migration from the point of placement. Limiting the length of the tube to short segments less than 4 cm may be a solution to the first problem. The make of the tube has to be related to the modern non-thrombogenic vascular prosthetic materials. Displacement of the tube from its insertion point may be prevented by giving the tube either a fenestrated or a corrugated external surface. The memory of the tube may be obtained by an inner deformable wire mesh consisting in crisscrossed structure with welded crossing points.

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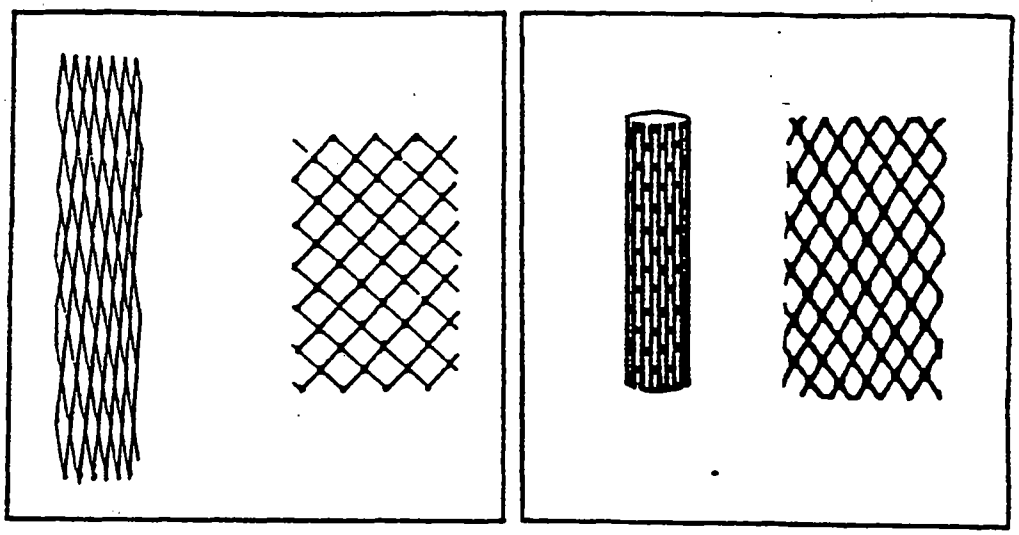
(Figure 1.)



This mesh should be made of silver, tantalum or stainless steel. Several wire diameters have to be experimented in each wire material so as to establish the optimum point between resistance to deformity and ability to retain the shape. The wire mesh is then covered with the vascular prosthetic material which has to have low thrombogenicity and high radial compliance. Porous polyurethane may prove suitable for this use. The material should cover the mesh inside and outside. The outer surface may contain multiple circumferential protuberances to assure anchorage to the vessel. Probably, multiple orifices or localized depresions on the outer surface may provide the same stability without the need of increasing the total tube wall thickness.(Figure 2.)

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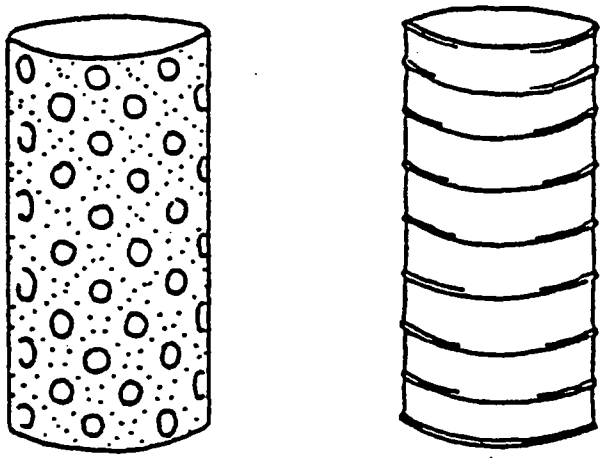
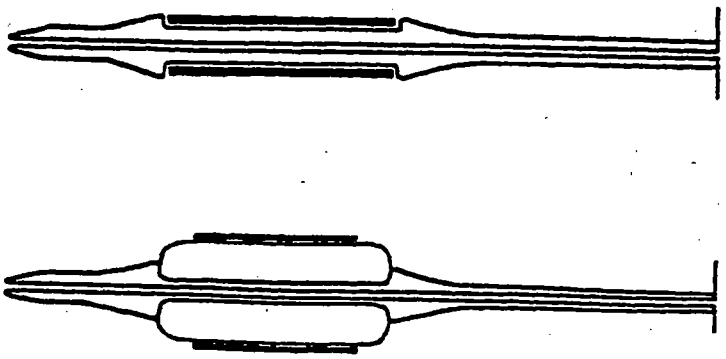


The tube should be mounted in the collapsed state over a modified Grüntzdig balloon catheter of adequate length and diameter. The leading and trailing extremes of the balloon have to be oversized so as to accommodate the tube over the balloon without protruding edges. (Figure 3)



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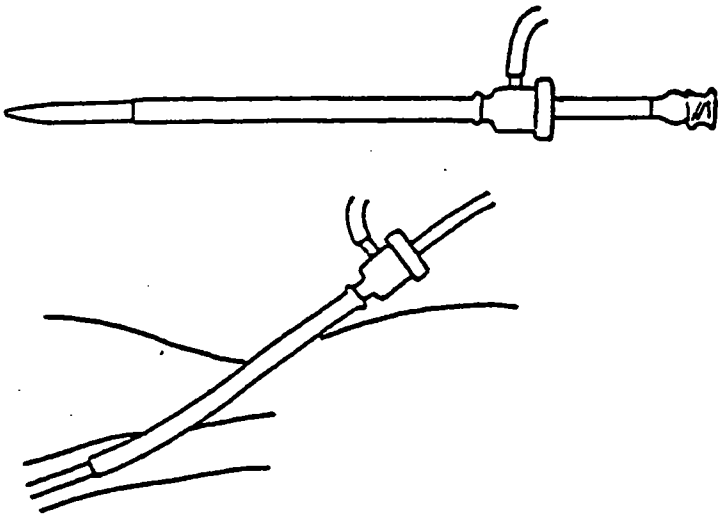
The whole system may be introduced in the femoral artery through an introducer sheath already in place. (Figure 4.)



The assembly is advanced through a wire which tip is beyond the area to be dilated.

The experimental project might be developed in three stages:

a.) Experimentation of different wire structures by changing mesh density, wire diatmeter and wire material to establish adequate dilating pressures, resistance to expansion and memory of the mesh.

b.) Placement of the tube in isolated cadaver arteries with stenotic arteriosclerotic lesions.

c.) Placement of the tube by percutaneous insertion into femoral arteries of laboratory 50 pound mongrel dogs, sheep or swine, in whom previous operative artificial iliac stenosis have been performed. The control of the tube patency is done by an adequately tailored schedule of aortograms performed by contralateral femoral catheterization. The animals are sacrificed at suitable intervals of time and gross and histopathological examination of the artery and tube is done.

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BIBLIOGRAPHY

1. Dotter CT, Judkins MP.: Transluminal treatment of arterio-sclerotic obstruction: Description of a new technique and preliminary report of its application. Circulation, Nov 1964, 30:654-670

2. Portsman W.: Ein Neven Korsett - Balloon Katheter zur transluminalen rekanalization nach Dotter unter besonderer Berücksichtigung von Obliterationen an der Beckenarteriem. Radiol Diag (Berl), 1973 14:239-274

3. Grüntzdig A, Hoppf H.: Percutane Rekanalization chronischel arterieller verschlüsse mit einem neven Dilatatiouskatheter. Modifikationder Dotter - technik. Dtsch Med Wochenschr, 1974. 99:2502-2505.

4. Gruntzdig A, Kumpe DA.: Technique of percutaneous transluminal angioplasty with the Grüntzdig balloon-catheter. AJR, April 1979. 132:547-552

5. Katzen TB, Chang J.: Percutaneous transluminal angioplasty with the Gruntzdig balloon catheter. Radiology, March 1979. 130:623-626

6. Mortarjeme A, Keifer JW, Zuska AJ.: Percutaneous transluminal angioplasty and case selection. Radiology June 1980, 135:573-581

7. Gruntzdig A, Kuhlmaun V, Vetter W, et al: Treatment of renovascular hypertension with percutaneous transluminal dilatation of a renal-artery stenosis. Lancet, April 1978 1:801-802

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8. Tegtmeyer CJ, Ray Dyer, Teates CA, Ayers C, Carey RM, Wellons HA, Stanton LW.: Percutaneous transluminal dilatation of the renal arteries. Radiology June 1980. 135:589-599

9. Dotter CT.: Transluminal Angioplasty: A long view. Radiology June 1980, 135:561-564

10. Colapinto RF, Harries-Janes EP, Wayne Johnston K. Percutaneous transluminal dilatation and recanalization in the treatment of peripheral vascular disease. Radiology 135, June 1980, 135:583-587

11. Castaneda-Zuniga WR, Formanek A, Tadavarthy M, Vlodaver Z, Edwards JE, Zollikofer C, Amplatz K. The mechanism of balloon angioplasty. Radiology June 1980, 135:565-571

Exhibit F

EXHIBIT F

RESEARCH PROJECT

EXPANDABLE VASCULAR ENDOPROSTHESIS

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VA Medical Center, Martinez, CA. 94553

Introduction:

All forms of intraluminal dilatation of stenotic lesions involve shearing and disruption of the wall components to achieve a wider lumen. In the case of arterial atherosclerotic lesions, the relatively incompressible plaque remains unaltered while the more elastic medial and adventitial layers stretch around the plaque. This phenomenon produces splitting of the wall layers usually at the level of the internal elastic lamina resulting in a partially detached plaque. The intima suffers fissuring and ther may be loss of underlying amorphous material into the lumen (1). Fortunately, the distending intraluminal pressure seems to hold the disrupted layers in place and thrombus deposition prevent significant embolization.

Dilatation of lesions composed by actively proliferating tissue such as neointimal hyperplasia in the case of vascular anastomotic stenosis and neoplastic tissue such as in esophageal, ureteral, bronchial and biliary malignant strictures is doomed to early restenoses if initially good results have been obtained. Sometimes, adequate dilatation is not achieved initially despite multiple dilatation attempts and the trial of different balloon configurations. Atherosclerotic lesions do not have the same mechanical characteristics throughout the arterial tree in relationship to their response to balloon dilatation. For example, it is now well known that plaques at the ostium of the renal arteries encompassing the adjacent aortic wall are unyielding to dilatation (2). Treatment of these lesions by balloon angioplasty have proven to be far less successful than distal renal atherosclerotic dilatations (2). The gross characteristics of the plaques involving the orifices of the celiac and mesenteric orifices is different from those involving the infrarenal aorta and iliac arteries. The former are edematous looking more elastic and do not contain a relatively high proportion of cholesterol and

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calcium (3). These features may explain some of the failed attempts of dilatation of proximal celiac and mesenteric stenoses. Carotid and vertebral artery atherosclerotic stenosis dilatation is theoretically contraindicated because of the inherent risk of embolic events. Nevertheless a number of vertebral dilatations have been reported without complications (4). Subclavian, innominate, common carotid and vertebral stenoses are relatively common in symptomatic patients in whom no surgery is warranted for a variety of reasons. These patients are potential candidates for angioplasty if the lesions to be dilated show no ulceration. Unfortunately the angiographic evidence of absence of ulceration is frequently false due to thrombi covering the ulcer. Even in case of absent ulceration, dilatation of plaques rich in calcium and cholesterol may produce emboli dangerous in the cerebral circulation while the same phenomenon is usuall clinically undetected in the lower extremities.

Recanalization of iliac lesions has been shown to be associated with a high incidence of significant embolisation (5) probably due to the large amount of thrombotic and atherosclerotic material to be mobilised. Long segment superficial femoral artery recanalisation has also poor results for the same reason and the lower flow rate in that vessel.

Venous access fistulas for hemodyalisis with anastomotic or post anastomotic stenosis have been treated with balloon dilatation (6). Nevertheless these lesions have been noted to be harder to dilate and have required balloon diameters larger than originally thought. Takayasu's arteritis and neurofibromatosis vascular stenoses have been treated by balloon angioplasty with variable results. In some patients early restenoses required repeated dilatations (7).

In summary, each failure of balloon dilatation is usually due to elastic recoil of highly fibrous lesions. In general recurrent stenosis is due to

actively proliferating tissue. The risk of embolization is insignificant in certain vascular territories but clearly precludes the use of angioplasty in others.

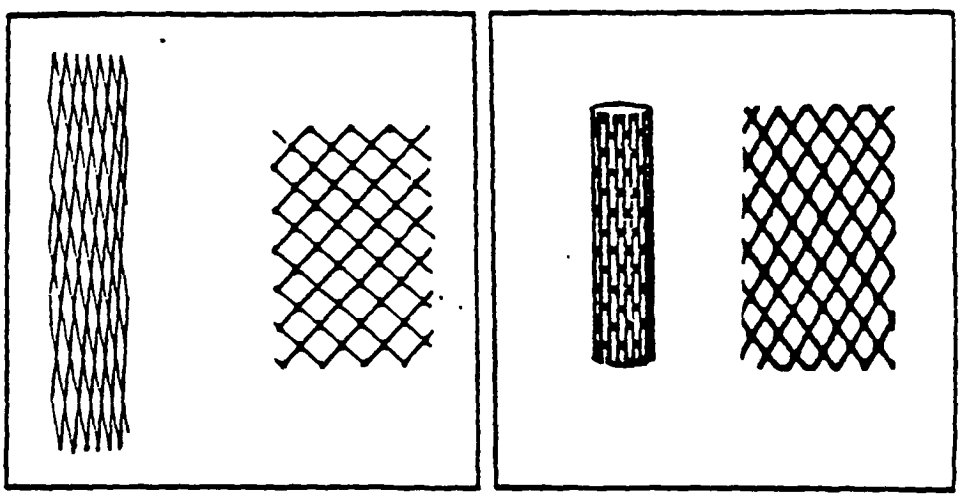
Endoluminal expendable prosthesis:

The idea of percutaneous placement of an endoluminal graft was first used by Dotter in 1969 (8). This author placed metallic coils inside of femoral arteries of dogs and showed long term patency. More recently the same author and others (9-10) have used metallic coils made of a heat sensitive alloy that allowed the coil to expand in place after percutaneous introduction. These authors also mentioned the potential application of this method in territories other than the vascular. Nevertheless, the biocompatibility and mechanical aspects of this material as well as cost considerations will need extensive and prolonged testing. One theoretical drawback of this method would be the lack of control on the reshaping of the coil after deposition. Excessive or insufficient pressure of the coil on the arterial wall may prove inadequate for lumen restoration particularly when a wide variety of stenotic shapes and wall compliances are considered. For the same reason, compactness of the coil may not be adequate in unyielding lesions and the possibility of perforation has to be considered. Finally if the coil reshapes in inadequate position occlusion of the tubular structure may ensue.

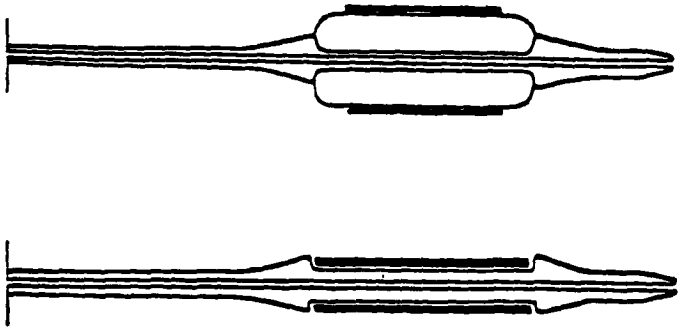
Proposed endoluminal prosthesis:

An expandable tube introduced percutaneously, mounted on a modified angioplasty balloon catheter will have the possibility of being delivered in place while the stenosis is being dilated. The tube would maintain the lumen, avoid dislodgement of loose material and give structural support to the wall.

The degree of expansion of the tube can be monitored both by pressure and fluoroscopy in the same way angioplasty is done. The prosthetic tube wall should be adequately thin so as to avoid reducing the lumen of the tubular structure to be dilated by excessively increasing the total wall thickness. Two theoretical general configurations based on the same principle have been devised: a tubular wire mesh similar to the popular toy "Chinese fingers" and an expandable metal tube with longitudinal fissures.



The first configuration could be fabricated out of silver, tantalum or stainless steel wire. Several wire diameters have to be tried to establish the optimum point between resistance to deformity and ability to retain shape. The cross points of the helical and antihelical wire coils should be welded in the expanded state and then the tube should be coated with teflon and heparin using the standard methods employed for vascular guide wires manufacturing. The tube should be compressed, mounted over a modified balloon angioplasty catheter with guards to protect the graft leading and trailing ends while the assembly is advanced within the skin.

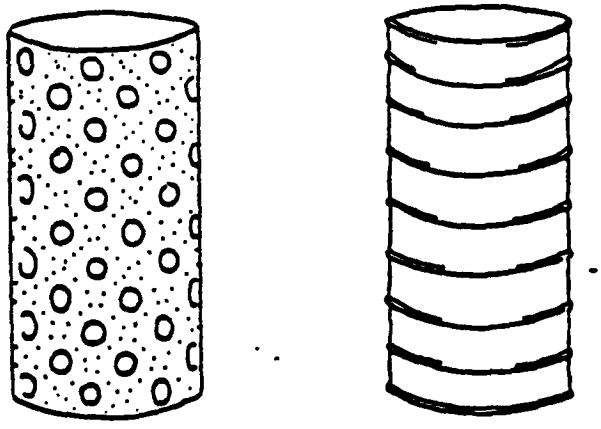


Once in place inflation of the balloon will expand the tube and the vessel or duct together. The spaces between wires will be occupied by extruded material providing anchorage to the graft. Shortening of the tube as it is being dilated will occur and it will be exponentially related to the degree of dilatation.

The second configuration is basically similar. The tube could initially be a thin walled silver, tantalum or stainless steel continuous tube in which alternating fissures such as shown in Fig. 1 have been done. This process may require sophisticated techniques such as electronic or laser etching. After expansion, the unfolded "bars" between fissures will twist and loss of length will result. Although the expanded tube wall will be thicker than the wire mesh tube the unexpanded tube wall will be smoother and thinner therefore allowing an easier introduction and positioning before inflation.

After testing either or both configurations for mechanical behavior, stability and biocompatibility a second phase of development should involve coating of the tubes with porous polyurethane or other biologically inert plastic. The plast coat should be thin and highly compliant so as not to interfere with mechanics of the tube. The tube could be coated in a continuous

fashion and the external surface could have ridges or knobs for peripheral anchoring. This configuration could be particularly adequate for non vascular ducts. The coating of the wire mesh tube could be done so as to leave holes or spaces between the wires, therefore allowing the inner surface of the dilated structure to be partially in direct contact with the lumen contents.



Theoretical drawbacks include:

a) Reduction of the longitudinal flexibility of the artery or duct.

b) Low or absent radial compliance of the graft.

c) Possibility of migration of the graft.

In the vascular system the tube lengths should be limited to probably no more than 4 cm. Longer areas of stenosis or occlusion could be dealt with tubes in tandem. Nevertheless the tube will be collapsible and probably inadequate for use in mobile areas such as the common femoral artery. A metal tube will have little or no radial compliance. Mismatch of radial compliance at the point of transition between host tissue and graft is of critical significance in the arterial system. Nevertheless highly sclerotic and calcified arteries have a substantial loss of radial compliance therefore the mismatch may be minimal or

nonsignificant. These considerations are even less critical in other organic tubular structures particularly when they are involved by neoplasms. Measures to prevent graft migration have been discussed above. The wire mesh tube without an extruded plastic coating on top will probably be very stable. The mesh will be "embedded" in the wall by pressure and the tissue surface between wires will most likely repithelialize covering the mesh completely.

Significance of the problem:

Although angioplasty has had a great expansion in its use and indications in the past 10 years, in many cases, it will prove inadequate as a long term solution for many applications. Nevertheless the impact on medical care costs is obvious and the savings in hospitalization time and patient suffering has been repeatedly proven. The latter is particularly significant in the older population with advance disease and limited survival time. In the terminal cancer patient, when neoplasms involve tubular structures, their patency usually will determine the length of survival. This is true in the urinary, biliary and respiratory tracts as well as in the esophagus and aqueduct. Large amounts of money, equipment and human resources are devoted to prolong the life of the elder and the cancer patient. If new methods to alleviate symptoms and palliate incurable disease can achieve these objectives at a lower medical cost, they deserve intensive research and development efforts.

REFERENCES

1) Block PC, Fallon JT, Kiser D. Experimental angioplasty: Lessons from the laboratory. AJR 1980, 135:907-912.

2) Cicuto KP, McLean GK, Ologa JA et al. Renal artery stenosis: Anatomic classification for percutaneous transluminal angioplasty. AJR 1981, 137:599-601.

3) Stoney RJ. Personal communication.

4) Mortarjeme A. Transluminal angioplasty. Castaneda-Zuniga WR, editor. Thieme-Stratton New York, New York. pp 200-202.

5) Ring EJ, Freiman DG, McLean GK et al. Percutaneous recanalization of common iliac artery occlusions: An acceptable complication rate? AJR 1982, 139:587.

6) Gordon DH, Glantz S, Butt KM et al. Treatment of stenotic lesions in dialysis access fistules and shunts by transluminal angioplasty. Radiology 1982, 143:53-58.

7) Castaneda-Zuniga WR and Amplatz KA. Transluminal angioplasty. Castaneda-Zuniga WR editor. Thieme-Stratton New York, New York, pp 89-92.

8) Dotter CT. Transluminally placed coilspring endarterial tube grafts: Long term patency in canine popliteal artery. Invest Radiol 1969, 4:329-332.

9) Dotter CT, Bushmann BM, McKinney MK, Rosch J. Transluminal expandable nitinol coil stent grafting: preliminary report. Radiology 1983, 147:259-260.

10) Cragg A, Lund G, Rysavy J et al. Non-surgical placement of arterial endoprosthesis. A new technique using nitinol wire. Radiology 1983, 147:261-263.

Exhibit G

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civ. No. 03-027-SLR
	)	
BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC.,	)	
	)	
Defendants.	)	

Steven J. Balick, Esq. and John G. Day, Esq. of Ashby & Geddes, Wilmington, Delaware. Of Counsel: Gregory L. Diskant, Esq., William F. Cavanaugh, Esq., Kim J. Landsman, Esq., Rosa E. Son, Esq. and Catherine A. Williams, Esq. of Patterson, Belknap, Webb & Tyler, LLP, New York, New York.

Josy W. Ingersoll, Esq. and John W. Shaw, Esq. of Young Conaway Stargatt & Taylor, LLP, Wilmington, Delaware. Of Counsel: John Desmarais, Esq. and Peter Armenio, Esq. of Kirkland & Ellis, New York, New York.

MEMORANDUM OPINION

Dated: June 3, 2005
Wilmington, Delaware

proof on the disputed issue is correct." Horowitz v. Fed. Kemper Life Assurance Co., 57 F.3d 300, 302 n.1 (3d Cir. 1995) (internal citations omitted). If the moving party has demonstrated an absence of material fact, the nonmoving party then "must come forward with 'specific facts showing that there is a genuine issue for trial.'" Matsushita, 475 U.S. at 587 (quoting Fed. R. Civ. P. 56(e)). The court will "view the underlying facts and all reasonable inferences therefrom in the light most favorable to the party opposing the motion." Pa. Coal Ass'n v. Babbitt, 63 F.3d 231, 236 (3d Cir. 1995). The mere existence of some evidence in support of the nonmoving party, however, will not be sufficient for denial of a motion for summary judgment; there must be enough evidence to enable a jury reasonably to find for the nonmoving party on that issue. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249 (1986). If the nonmoving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to judgment as a matter of law. See Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986).

IV. DISCUSSION

A. BSC's Motion For Summary Judgment That The Asserted Claims Of The '762 Patent Are Invalid

Under 35 U.S.C. § 102(b), "[a] person shall be entitled to a patent unless the invention was patented or described in a printed publication in this or a foreign country . . . more than

one year prior to the date of the application for patent in the United States." BSC argues that the '762 patent is invalid as anticipated by the Palmaz Monographs, which, according to BSC, were printed publications that were available more than a year prior to Dr. Palmaz filing the application that gave rise to the '762 patent. Cordis argues that the Palmaz Monographs are not printed publications because they were not publicly accessible.

"The statutory phrase 'printed publication' has been interpreted to mean that, before the critical date, the reference must have been sufficiently accessible to the public interested in the art; dissemination and public accessibility are the keys to the legal determination whether a prior art reference was 'published.'"[7] In re Cronyn, 890 F.2d 897, 1160 (Fed. Cir. 1986). Whether something is a "printed publication" is determined on a case by case basis, requiring inquiry into the facts and circumstances of the references' disclosure to the public. In re Klopfenstein, 380 F.3d 1345, 1350 (Fed. Cir. 2004).

A court should also consider whether or not the "printed publication" was the subject of confidentiality agreements or whether the disclosing party had "a reasonable expectation that

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[7]The relevant "public" consists of those individuals who would be interested in the invention, or the relevant art. Cooper Cameron Corp. v. Kvaerner Oilfield Products, Inc., 291 F.3d 1317, 1324 (Fed. Cir. 2002).

the information [would] not be copied." In re Klopfenstein, 380 F.3d at 1351. "Professional or behavioral norms [that] entitle a party to a reasonable expectation that the information displayed will not be copied" can also be evidence that something is not a "printed publication." Id. On the other hand, "evidence of business practice that was sufficient to prove [a document] was widely available and accessible to the interested public" can be sufficient to prove that the document was publicly accessible. Cosntant v. Advanced Micro-Devices, Inc., 848 F.2d 1560, 1569 (Fed. Cir. 1988).

Dr. Palmaz distributed the 1980 Monograph as a handout to his colleagues at the VA Medical Center during a presentation. There is no evidence that this was a public presentation, analogous to a presentation at a conference. See, e.g., Mass. Inst. of Tech. v. AB Fortia, 774 F.2d 1104, 1108-09 (Fed. Cir. 1985). The presentation and distribution was of an internal character, and there is no evidence that those of interest could have found the document, much less gained access to it. See Donald S. Chisum, Chisum On Patents § 3.04[2] (2002). There is no evidence that Dr. Palmaz's intent was anything other than getting feedback to further his research, nor evidence that he expected anything less than full confidentiality from these colleagues.

Dr. Palmaz also distributed the 1980 Monograph to three companies in an effort to attract funding and a co-developer. In Garrett Corp. v. United States, 422 F.2d 874, 878 (Ct. Cl. 1970), the court stated that "distribution to commercial companies without restriction on use clearly" constitutes publication. In that case, 80 copies of an unclassified, unrestricted government report were distributed to government agencies and private companies. Id. The report was made available to government contractors upon request free of charge. Id. In this case, there is no evidence that either Vascor, Shiley or Cook would have distributed, or in fact did distribute, the 1980 Monograph outside of the company. Furthermore, Dr. Palmaz has testified that he expected the companies to keep the monograph confidential, as it was his perception that confidentiality was an industry practice. Absent some indication that these companies would have freely distributed the monograph, the court declines to find that the monograph was accessible to those interested, solely because it was given to the companies.

The 1983 Monograph was given to three people, two of whom were employed at UTHSCSA. Dr. Palmaz's intent again was to further his research and facilitate his employment at UTHSCSA, neither of which evidences an intent to make his invention publicly accessible. There is no evidence that Dr. Palmaz's disclosure made the monograph accessible to anyone other than

those at UTHSCSA or Mr. Schultz. Nor is it evident that anyone at UTHSCSA could access the monograph, as opposed to limited access by Dr. Reuter and Mr. Peters. Like his distribution at the VA Medical Center, Dr. Palmaz's distribution to UTHSCSA was an internal disclosure. Even assuming that those of interest could have found out about the 1983 Monograph, there is no indication that UTHSCSA would have freely distributed the 1983 Monograph. Therefore, BSC's motion for summary judgment is denied, as the Palmaz Monographs are not prior art under § 102(b).

B. Cordis' Motion For Summary Judgment That The Asserted Claims Of The '762 Patent Are Not Invalid

Assuming for the purposes of argument that the Palmaz Monographs are prior art, Cordis argues that BSC is precluded from asserting them as invalidating prior art in this case.[8] Specifically, Cordis contends that issue preclusion prevents BSC from asserting its invalidity defense, because the jury in the 97-550 case found the '762 patent to be valid.[9] BSC contends

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[8]Cordis also argues that BSC's experts are applying the wrong invalidity standard in their discussions of enablement and written description. After reviewing the expert reports of Dr. Moore, Dr. Goldberg and Dr. Benet, the court concludes that these experts are not applying an incorrect standard. The experts address whether or not the '762 patent enables and/or describes a drug-eluting stent. To the extent that Cordis claims that drug-eluting stents are covered by the '762 patent, the experts' analysis is appropriate.

[9]Cordis also argues that claim preclusion prevents BSC from bringing an invalidity defense. However, the Federal Circuit has

Exhibit H

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/007,627 + 90/008780 + 90/008797	07/13/2005	4739762	52734-036A	9591

32116 7590 05/07/2008

EXAMINER

WOOD, PHILLIPS, KATZ, CLARK & MORTIMER
500 W. MADISON STREET
SUITE 3800
CHICAGO, IL 60661

ART UNIT	PAPER NUMBER

DATE MAILED: 05/07/2008

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

[redacted]

THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS

KENNETH L. CAGE
McDERMOTT WILL & EMERY LLP
600 THIRTEENTH STREET, N.W.
WASHINGTON, DC 20005-3096

EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO 90/008780 + 90/008797 + 90/007627
PATENT NO. 4,739,762
ART UNI 3993

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified ex parte reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the ex parte reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

[redacted]

THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS

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VIDAS,ARRETT & STEINKRAUS
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EDEN PRAIRIE, MN 55344

EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO 90/008797 + 90/007627 + 90/008780
PATENT NO. 4,739,762
ART UNI 3992

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified ex parte reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the ex parte reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Office Action in Ex Parte Reexamination	**Control No.** 90/007,627; 90/008,780, 90/008,797	**Patent Under Reexamination** 4739762	
	Examiner BEVERLY M. FLANAGAN	**Art Unit** 3993	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

a☐ Responsive to the communication(s) filed on _____. b☐ This action is made FINAL.
c☒ A statement under 37 CFR 1.530 has not been received from the patent owner.

A shortened statutory period for response to this action is set to expire 2 month(s) from the mailing date of this letter. Failure to respond within the period for response will result in termination of the proceeding and issuance of an *ex parte* reexamination certificate in accordance with this action. 37 CFR 1.550(d). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).** If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Information Disclosure Statement, PTO/SB/08.
3. ☐ Interview Summary, PTO-474.
4. ☐ _____.

Part II SUMMARY OF ACTION

1a. ☒ Claims *1-12,14-23,25-44,51 and 54* are subject to reexamination.
1b. ☒ Claims *13,24,45-50,52,53 and 55-59* are not subject to reexamination.
2. ☐ Claims _____ have been canceled in the present reexamination proceeding.
3. ☐ Claims _____ are patentable and/or confirmed.
4. ☒ Claims *1-12, 14-23, 25-44, 51 and 54* are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ The drawings, filed on _____ are acceptable.
7. ☐ The proposed drawing correction, filed on _____ has been (7a)☐ approved (7b)☐ disapproved.
8. ☐ Acknowledgment is made of the priority claim under 35 U.S.C. § 119(a)-(d) or (f).
   a)☐ All b)☐ Some* c)☐ None of the certified copies have
   1☐ been received.
   2☐ not been received.
   3☐ been filed in Application No. _____.
   4☐ been filed in reexamination Control No. _____.
   5☐ been received by the International Bureau in PCT application No. _____.
   * See the attached detailed Office action for a list of the certified copies not received.
9. ☐ Since the proceeding appears to be in condition for issuance of an *ex parte* reexamination certificate except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte* Quayle, 1935 C.D. 11, 453 O.G. 213.
10. ☐ Other: _____

cc: Requester (if third party requester)

DETAILED ACTION

Reexamination Procedures

In order to ensure full consideration of any amendments, affidavits or declarations, or other documents as evidence of patentability, such documents must be submitted in response to this Office action. Submissions after the next Office action, which is intended to be a final action, will be governed by the requirements of 37 C.F.R. 1.116, after final rejection and 37 C.F.R. 41.33 after appeal, which will be strictly enforced.

Extensions of time under 37 C.F.R. 1.136(a) will not be permitted in these proceedings because the provisions of 37 C.F.R. 1.136 apply only to "an applicant" and not to parties in a reexamination proceeding. Additionally, 35 U.S.C. § 305 requires that reexamination proceedings "will be conducted with special dispatch" (37 C.F.R. 1.550(a)). Extension of time in *ex parte* reexamination proceedings are provided for in 37 C.F.R. 1.550(c).

The patent owner is reminded of the continuing responsibility under 37 C.F.R. 1.565(a) to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving Patent No. 4,739,762 throughout the course of this reexamination proceeding. The third party requester is also reminded of the ability of similarly apprise the Office of any such activity or proceeding throughout the course of this reexamination proceeding. See MPEP §§ 2207, 2282 and 2286.

Patent owner is notified that any proposed amendment to the specification and/or claims in this reexamination proceeding must comply with 37 C.F.R. 1.530(d)-(j), must

be formally presented pursuant to 37 C.F.R. 1.52(a) and (b), and must contain any fees required by 37 C.F.R. 1.20(c).

After the filing of a request for reexamination by a third party requester, any document filed by either the patent owner or the third party requested must be served on the other party (or parties where two or more third party requested proceedings are merged) in the reexamination proceeding in the manner provided in 37 C.F.R. 1.248. See 37 C.F.R. 1.550(f).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12, 14-23, 25-44, 51 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by the 1980 Monograph.

The examiner finds the 1980 Monograph to be a printed publication pursuant to 35 U.S.C. § 102(b). Requester has provided considerable evidence that the 1980 Monograph was both publicly accessible and widely disseminated prior to the critical date of November 7, 1984. Dr. Palmaz provided a declaration under 37 C.F.R. 1.131 in a previous reexamination of U.S. Patent No. 4,739,762 that establishes that the 1980 Monograph was provided to several companies during the course of obtaining research

funds for the invention.[1] Various excerpts from trial testimony and depositions in litigation involving U.S. Patent No. 4,739,762, all supplied as Exhibits to the instant reexamination request, further chronicle Dr. Palmaz's interactions with the several companies.[2] It is also noted that confidentiality agreements were not executed with any of the companies contacted.[3] The examiner concludes that the evidence presented in the request demonstrates that the 1980 Monograph was disseminated and publicly available more than one year prior to the critical date of November 7, 1984 and thus, qualifies as a prior art printed publication under 35 U.S.C. § 102(b).

The 1980 Monograph teaches an expandable intraluminal graft which has a thin wall surface that is smooth prior to expansion (see Figs. 1 and 3 and page 367 of the 1980 Monograph). The 1980 Monograph teaches an intraluminal tubular structure that is capable of expansion (see page 367 and Fig. 3 of the 1980 Monograph) and described a slotted tube stent with first and second ends (see Fig. 3 of the 1980 Monograph). Fig. 3 shows a thin thickness that is smooth in a first diameter and the slots, which form peaks and valleys, are formed therein are aligned along the longitudinal axis of the stent (see also Fig. 1 of the 1980 Monograph). The 1980 Monograph teaches a stent that has a first diameter on a balloon and is delivered intraluminally through a body passageway to treat a stenosis (see Figs. 1, 3 and 4 and pages 248,351 and 366-367 of the 1980 Monograph). The 1980 Monograph teaches an expandable tubular structure having a shape memory to avoid recoil and it delivered

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[1] The declaration was provided in Reexamination Control No. 90/002,493 and has been submitted as Exhibit M in the instant reexamination request.
[2] See, e.g., Exhibits I-R of the instant reexamination request.
[3] See the instant reexamination request, at page 7, line 20.

by a balloon catheter, whose inflation can be variably controlled (see Fig. 3 and pages 265, 266 and 267 of the 1980 Monograph).

Claims 1-12, 14-23, 25-44, 51 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by the 1983 Monograph.

The examiner finds the 1983 Monograph to be a printed publication pursuant to 35 U.S.C. § 102(b). Requester has provided considerable evidence that the 1983 Monograph was both publicly accessible and widely disseminated prior to the critical date of November 7, 1984. Dr. Palmaz provided a declaration under 37 C.F.R. 1.131 in a previous reexamination of U.S. Patent No. 4,739,762 that establishes that the 1983 Monograph was provided to several companies during the course of obtaining research funds for the invention.[4] Various excerpts from trial testimony and depositions in litigation involving U.S. Patent No. 4,739,762, all supplied as Exhibits to the instant reexamination request, further chronicle Dr. Palmaz's interactions with the several companies.[5] It is also noted that confidentiality agreements were not executed with any of the companies contacted.[6] The examiner concludes that the evidence presented in the request demonstrates that the 1983 Monograph was disseminated and publicly available more than one year prior to the critical date of November 7, 1984 and thus, qualifies as a prior art printed publication under 35 U.S.C. § 102(b).

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[4] The declaration was provided in Reexamination Control No. 90/002,493 and has been submitted as Exhibit M in the instant reexamination request.
[5] See, e.g., Exhibits I-R of the instant reexamination request.
[6] See the instant reexamination request, at page 7, line 20.

The 1983 Monograph teaches an expandable intraluminal graft which has a thin wall surface that is smooth prior to expansion (see page 350 of the 1983 Monograph). The 1983 Monograph teaches an intraluminal tubular structure that is capable of expansion and described a slotted tube stent with first and second ends (see pages 349-350 of the 1983 Monograph). A thin thickness that is smooth in a first diameter and the slots, which form peaks and valleys, are formed therein are substantially parallel with and aligned along the longitudinal axis of the stent (see pages 349-350 of the 1983 Monograph). The 1983 Monograph teaches a stent that has a first diameter on a balloon and is delivered intraluminally through a body passageway to treat a stenosis (see Figs. 1, 3 and 4 and pages 248,351 and 366-367 of the 1980 Monograph). The 1983 Monograph teaches a tubular member having a second, expanded and deformed diameter upon the application from the interior of the tubular member of radially, outwardly extending force, by inflating the balloon portion of the catheter, which second diameter is variable and controlled by the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to expand the lumen of the passageway (see page 350 of the 1983 Monograph). The 1983 Monograph teaches an expandable tubular structure having a shape memory to avoid recoil and it delivered by a balloon catheter, whose inflation can be variably controlled (see pages 348-49 of the 1983 Monograph).

Scope of Reexamination

Since requester did not request reexamination of claims 13, 24, 45-50, 52, 53 and 55-59 and did not assert the existence of a substantial new question of patentability (SNQP) for such claims (see 35 U.S.C. § 311(b)(2); see also 37 CFR 1.915b and 1.923), such claims will not be reexamined. This matter was squarely addressed in *Sony Computer Entertainment America Inc., et al. v. Jon W. Dudas*, Civil Action No. 1:05CV1447 (E.D.Va. May 22, 2006), Slip Copy, 2006 WL 1472462. (Not Reported in F.Supp.2d.) The District Court upheld the Office's discretion to not reexamine claims in an *inter partes* reexamination proceeding other than those claims for which reexamination had specifically been requested. The Court stated:

> To be sure, a party may seek, and the PTO may grant, *inter partes* review of each and every claim of a patent. Moreover, while the PTO in its discretion may review claims for which *inter partes* review was not requested, nothing in the statute compels it to do so. To ensure that the PTO considers a claim for *inter partes* review, § 311(b)(2) requires that the party seeking reexamination demonstrate why the PTO should reexamine each and every claim for which it seeks review. Here, it is undisputed that Sony did not seek review of every claim under the '213 and '333 patents. Accordingly, Sony cannot now claim that the PTO wrongly failed to reexamine claims for which Sony never requested review, and its argument that AIPA compels a contrary result is unpersuasive.

(Slip copy at page 9.)

The *Sony* decision's reasoning and statutory interpretation apply analogously to *ex parte* reexamination, as the same relevant statutory language applies to both *inter partes* and *ex parte* reexamination. 35 U.S.C. § 302 provides that the *ex parte* reexamination "request must set forth the pertinency and manner of applying cited prior

art to every claim for which reexamination is requested" (emphasis added), and 35 U.S.C. § 303 provides that "the Director will determine whether a substantial new question of patentability affecting any claim of the patent concerned is raised by the request..." (Emphasis added). These provisions are analogous to the language of 35 U.S.C. § 311(b)(2) and 35 U.S.C. § 312 applied and construed in *Sony*, and would be construed in the same manner. As the Director can decline to reexamine non-requested claims in an *inter partes* reexamination proceeding, the Director can likewise do so in *ex parte* reexamination proceeding. See *Notice of Clarification of Office Policy To Exercise Discretion in Reexamining Fewer Than All the Patent Claims* (signed Oct. 5, 2006) 1311 OG 197 (Oct. 31, 2006). See also MPEP § 2240, Rev. 5, Aug. 2006.

Therefore, claims 13, 24, 45-50, 52, 53 and 55-59 were not be reexamined in this *ex parte* reexamination proceeding.

NOTICE RE PATENT OWNER'S CORRESPONDENCE ADDRESS

Effective May 16, 2007, 37 CFR 1.33(c) has been revised to provide that:

> The patent owner's correspondence address for all communications in an *ex parte* reexamination or an *inter partes* reexamination is designated as the correspondence address of the patent.
>
> *Revisions and Technical Corrections Affecting Requirements for Ex Parte and Inter Partes Reexamination*, 72 FR 18892 (April 16, 2007)(Final Rule)

The correspondence address for any pending reexamination proceeding not having the same correspondence address as that of the patent is, by way of this revision to 37 CFR 1.33(c), automatically changed to that of the patent file as of the effective date.

This change is effective for any reexamination proceeding which is pending before the Office as of May 16, 2007, including the present reexamination proceeding, and to any reexamination proceeding which is filed after that date.

Parties are to take this change into account when filing papers, and direct communications accordingly.

In the event the patent owner's correspondence address listed in the papers (record) for the present proceeding is different from the correspondence address of the patent, it is strongly encouraged that the patent owner affirmatively file a Notification of Change of Correspondence Address in the reexamination proceeding and/or the patent (depending on which address patent owner desires), to conform the address of the proceeding with that of the patent and to clarify the record as to which address should be used for correspondence.

Telephone Numbers for reexamination inquiries:

Reexamination and Amendment Practice	(571) 272-7703
Central Reexam Unit (CRU)	(571) 272-7705
Reexamination Facsimile Transmission No.	(571) 273-9900

Conclusion

Please mail any communications to:

Attn: Mail Stop "Ex Parte Reexam"
Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Please FAX any communications to:

(571) 273-9900
Central Reexamination Unit

Please hand-deliver any communications to:

Customer Service Window
Attn: Central Reexamination Unit
Randolph Building, Lobby Level
401 Dulaney Street
Alexandria, VA 22314

Any inquiry concerning this communication or earlier communications from the Examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number (571) 272-7705.

Signed:

/Beverly M. Flanagan/

Beverly M. Flanagan
CRU Examiner
GAU 3993
(571) 272-4766

Conferee /JMC/

Conferee _____

Exhibit I

IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

- - -

CORDIS CORPORATION, Plaintiff v. MEDTRONIC AVE, INC., BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC., Defendant	:	CIVIL ACTION NO. 97-550 (SLR) (Consolidated)
MEDTRONIC AVE, INC., Plaintiff v. CORDIS CORPORATIKN, JOHNSON & JOHNSON and EXPANDABLE GRAFTS PARTNERSHIP Defendants	:	CIVIL ACTION NO. 97-700 (SLR)
BOSTON SCIENTIFIC CORPORATION, Plaintiff V. ETHICON, INC., CORDIS CORPORATION and JOHNSON & JOHNSON INTERVENTIONAL SYSTEMS CO., Defendants	:	CIVIL ACTION NO. 98-19 (SLR)
CORDIS CORPORATION, Plaintiff V. BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC., Defendants	:	CIVIL ACTION NO. 98-197 (SLR)

- - -

Wilmington, Delaware
Wednesday, September 22, 2004
8:07 o'clock, a.m.
***Telephone conference

- - -

BEFORE: HONRABLE SUE L. ROBINSON, Chief Judge

- - -

Valerie J. Gunning
Official Court Reporter

APPEARANCES:

ASHBY & GEDDES
BY: STEVEN J. BALICK, ESQ.

-and-

PATTERSON, BELKNAP, WEBB & TYLER LLP
BY: EUGENE M. GELERNTER, ESQ.,
MICHAEL TIMMONS, ESQ. and
(New York, New York)

-and-

JOHNSON & JOHNSON.
BY: ERIC I. HARRIS, ESQ.

Counsel for Cordis Corporation

MORRIS, NICHOLS, ARSHT & TUNNELL
BY: KAREN JACOBS LOUDEN, ESQ.

-and-

McDERMOTT, WILL & EMERY
BY: MICHAEL UNDERHILL, ESQ.,
MARK DAVIS, ESQ.
(Washington, D.C.)

Counsel for Medtronic AVE, Inc.

YOUNG, CONAWAY, STARGATT & TAYLOR
BY: JOSY W. INGERSOLL, ESQ.

-and-

KENYON & KENYON
BY: GEORGE BADENOCH, ESQ. and
MARK CHAPMAN, ESQ.
(New York, New York)

Counsel for Boston Scientific Corporation,

- - -

PROCEEDINGS

.

(REPORTER'S NOTE: The following telephone conference was held in chambers, beginning at 8:07 a.m.)

THE COURT: Good morning, counsel. This is Judge Robinson. Valerie is here as our Court Reporter.

The purpose of this telephone conference was to decide where we go from here and what still needs to be decided and how we go about resolving the remaining issues.

I apologize for giving you so little time to think about that in light of my latest opinion, but in my estimation, we've got three infringement issues and a couple damage issues. I know we still have the to flexibly connect issue that I guess we need to decide in connection with the '984.

I still have on my list issues revolving around lost profit damages and a reasonable royalty and then, of course, the two issues that I addressed in my opinion that was issued yesterday, the substantially uniform thickness and smooth surface limitations.

So I don't know whether you've had time to digest it and think about it,, but this is the time to tell me your

thoughts, and let's start with plaintiffs' counsel.

MR. GELERNTER: Thank you, your Honor. This is Gene Gelernter from from Patterson Belknap for Cordis.

First, I'd like to thank the Court for permitting this conference to take place by phone. We asked the Court if we could have the conference by phone to accommodate Mr. Diskant because he's ill and we were hoping that he would be able to participate by phone. It turns out that he was diagnosed yesterday as having pneumonia and he's not going to be able to join us this morning, but we do want to thank the Court for permitting us to appear by phone.

We've given some thought, your Honor, to where we should be going next in this case, and we think that the decision yesterday and the recent expert discovery that we've had on validity simplify matters considerably and make this case ripe for disposition on dispositive motions.

First, on the infringement issue, we think yesterday's decisions on claim construction, prosecution history estoppel, first of all, they clearly establish that Cordis is entitled to rely on the doctrine of equivalents, and we think the decision makes it appropriate to reinstate the verdict of the jury from four years ago.

We'd be prepared to submit a motion on that issue within one week from this coming Monday by October 4th. By the same token, on validity, we think the recent expert

depositions show that the claim construction -- the change in claim construction, the revised construction, doesn't change the issues or the outcome on validity, and we have case law that we'll cite to your Honor which shows that in these circumstances, summary judgment is appropriate.

So in our view, on both the infringement side of the case and on the validity side of the case, we think the case is ripe for disposition on summary judgment. We would be prepared to brief both issues one week from Monday, October 4th, and would propose that the parties proceed with briefing in the normal schedule.

One other matter. During the e-mail that the Court sent on May 28th, it stated that it was preserving time for trial in this case, if trial needs to go forward, during the eight-week period that the Court has set aside for trial.

That eight-week period, as I understand it, begins on January 24th, 2005 and ends on March 18th. We think that that's a good idea. We welcome that and we would ask the Court to continue to preserve space during that period for trial in this case if it's necessary. All of the parties are available during that period, and if the motions don't resolve the case, we think it could be resolved then.

The remaining issues that would need to be tried,

in light of the file history with the evidentiary question put to the jury.

The evidence put to the jury was under a different claim construction and a different unlimited equivalents instruction, with no estoppel instruction.

We now have a new bright-line test of a hundred-percent variation. We have to develop the record for the jury to decide that question. The question of what should be the instruction has now been decided by the Federal Circuit and your Honor. We have a new literal construction. We also have a new bright-line test. That was not the ruling before, at the time that the evidence was previously put to the jury.

MR. GELERNTER: Your Honor, it's just not the way the case was tried. Everyone put in their evidence, and then the Court was going to determine on the prosecution history record whether there was an estoppel based on the evidence presented.

I think that's already -- you know, a ship that has sailed. I don't think there's any basis for a new opportunity for defendants to put in additional evidence, and I think the record that's already presented is the record, and that under the reconstruction, it requires entry of judgment in light of your Honor's ruling on prosecution history estoppel.

THE COURT: All right. Well, let me give you the decisions I have made.

Number one, we will address the to flexibly connect issue on the papers, and if Medtronic wants to submit supplemental briefing, I suggest that be done promptly, and, Cordis, within the next two weeks, and Cordis can have two weeks to respond to that.

Damages will be bifurcated until we have addressed as a final matter validity and infringement. I think the trial schedule is set.

Validity. Cordis can certainly go forward and file its motion, summary judgment motion on validity. And if you feel compelled to take 30 days to respond, that is fine, and I will take the time I need to resolve it.

With respect to infringement, the question of whether there should be more expert discovery, and at this point I just want to make sure, the expert discovery that -- the expert record that defendants are seeking has to do solely with this hundred-percent variation, whether, in fact, it's present or not in the accused devices.

MR. BADENOCH: That's correct, your Honor.

THE COURT: And so the question is whether the defendant should have the opportunity to pursue that additional discovery as opposed to reviewing the infringement issue in light of the claim construction on the record that

was made at trial.

MR. BADENOCH: That's correct, your Honor. There has never been a jury verdict on this new bright-line test.

Now, since plaintiff has the burden of proof, we were thinking it makes sense for them to supplement with their, the views of their experts on that issue, and then we would supplement with the views and evidence of our experts on that issue, and then we would take depositions.

THE COURT: All right. Well, by Monday I will give you my thoughts on whether there should be additional expert discovery, but I think other than that, I think we're on board with all of the other issues. It is just the infringement issue, as to whether there should be a motion practice before supplemental expert discovery or not, and whether there should be supplemental expert discovery.

So let me think on that and I will issue something on, no later than Monday.

MR. UNDERHILL: Your Honor, I have one more issue, if I may, please.

THE COURT: Yes. And who is there?

MR. UNDERHILL: This is Mike Underhill.

THE COURT: Yes?

MR. UNDERHILL: One of the issues that has been suggested in papers filed by Cordis is a credibility attack

on one of Medtronic's experts, Dr. Ersek. And the credibility issue apparently arises out of a conversation or conversations between Dr. Ersek and his son-in-law and Mr. Diskant and Mr. Gelernter.

And we, I guess, would appreciate any guidance that the Court might have on how to proceed with this.

What we would suggest is that Cordis be given a date by which it informs us whether it does intend to press these credibility issues that it has raised arising out of any communications with Patterson Belknap.

If Cordis does attempt to raise those credibility issues, we believe that we would need to request a deposition of Mr. Diskant and/or Mr. Gelernter. On the other hand, if Cordis informs us that it is not going to in any way use the communications between Dr. Ersek and Patterson Belknap for any part of a credibility challenge, then it would seem that the issue is then irrelevant and we would not need the depositions.

THE COURT: All right. Let's hear from Cordis.

MR. GELERNTER: Your Honor, I would hope and expect that that entire issue would go by the wayside as the result of the case-dispositive motion that we expect to file on validity on October 4th.

Our position would be that any dates for forming (inaudible) on that issue or at least any depositions,

Exhibit J

- VOLUME E -
IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION, : CIVIL ACTION
Plaintiff :
vs. :
MEDTRONIC AVE, INC., BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC., :
Defendants : NO. 97-550 (SLR)

BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC., : CIVIL ACTION
Plaintiffs :
vs. :
ETHICON, INC., CORDIS CORP. and JOHNSON & JOHNSON INTERVENTIONAL SYSTEMS CO., :
Defendants : NO. 98-19 (SLR)

CORDIS CORPORATION, : CIVIL ACTION
Plaintiff :
vs. :
MEDTRONIC AVE, INC., BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC., :
Defendants : NO. 98-197 (SLR)

Wilmington, Delaware
Wednesday, March 23, 2005
9:25 o'clock, a.m.

BEFORE: HONORABLE SUE L. ROBINSON, Chief Judge, and a jury

Valerie J. Gunning and
Leonard A. Dibbs,
Official Court Reporters

APPEARANCES:

ASHBY & GEDDES
BY: STEVEN J. BALICK, ESQ.

-and-

PATTERSON, BELKNAP, WEBB & TYLER LLP
BY: GREGORY L. DISKANT, ESQ.,
EUGENE M. GELERNTER, ESQ.,
WILLIAM F. CAVANAUGH, JR., ESQ.,
MICHAEL TIMMONS, ESQ. and
SCOTT HOWARD, ESQ.
(New York, New York)

-and-

JOHNSON & JOHNSON
BY: ERIC I. HARRIS, ESQ.

Counsel for Cordis Corporation

YOUNG, CONAWAY, STARGATT & TAYLOR
BY: JOSY W. INGERSOLL, ESQ.

-and-

KENYON & KENYON
BY: GEORGE BADENOCH, ESQ.,
MARK CHAPMAN, ESQ. and
WALTER HANLEY, ESQ.
(New York, New York)

Counsel for Boston Scientific Corporation

PROCEEDINGS

(Proceedings commenced at 9:25 a.m., and the following occurred without the presence of the jury.)

MR. BADENOCH: Good morning, your Honor.

THE COURT: Good morning. You can keep talking. I just need to move some of these things out of my way.

All right.

MR. BADENOCH: We did prepare some language that we believe should be given to the jury as an instruction at the beginning on the business of referring to the absence of Brian Brown. And counsel and I have agreed on this, but we've scribbled up our form in which we prepared the agreement.

It might be better if I read it or I can hand it up. But what it says is, this is a timed trial in which the total time for each party to present its case is limited. Sometimes a party does not call a witness on the list of witnesses you read at the outset of the case. You are not to infer anything from that.

THE COURT: All right.

MR. BADENOCH: I will hand this up.

THE COURT: Hand it up, yes, then I will make sure I can read it as well as you did, Mr. Badenoch.

(Mr. Badenoch handed a document to the Court.)

THE COURT: Yes, I think I have it.

MR. BADENOCH: The other thing, your Honor, we had -- we're down to just a very few extremely minor things on the verdict form and the instruction, and I really think this is just clarity.

In the verdict form, where it says Claim 23 of the '762 patent requiring that the wall of, now it says a tubular member, and we want it to say the tubular member, which conforms, I think, to several other places throughout the instruction. And we feel, since there's clearly one tubular member in the accused stent that has been, as it has been presented to the jury, that that would be clearer.

I really think it's non-substantive. Counsel has said, Well, no, it departs from the claim construction, and I don't -- it did not seem to me that that was correct.

THE COURT: Well, I guess if it's non-substantive and if it isn't in dispute, and the claim construction reads an and we're going to the jury this morning, I wasn't confident that I wanted to go to the trouble of changing the to an every place it said

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easily be expanded by about 50 percent beyond its original diameter.

It doesn't mean it's only 50 percent as a possibility here. That's not what he says. It can be, by up to about 50 percent.

Then he says, the sleeves are formed to be a size appropriate for the implant being made. Appropriate. That doesn't mean it's the same size so that you shred the artery.

Then it says, the strands and apertures are sized proportionately, proportionately. That doesn't mean the same size.

There's no reason to think that Dr. Ersek would want to make his device in such a way that you plow it in like some sort of -- something with a wall surface that's too thick, too much crossing profile for your lumen that you would plow it in there with an effort to cut or shred it. That just doesn't make any sense.

Let's continue back with the claim, if we could. The claim goes on, the device has to have a second diameter. The second diameter has to be expandable or has to expand. It has to be expanded when you put a force inside that goes radially outward, okay. And it has to, the force has to be variable and,

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dependent on how much force, that's how much expansion you get. It's controllably expandable, as you heard a lot about there.

And, finally, after you expand it, you have to have it stay expanded and deformed so that it supports or expands the artery that it goes in.

And then Claim 23 adds, as you've heard, the additional requirement that the surface be smooth in the first diameter.

So that's what we're talking about. That claim on that expandable device, capable of certain uses, but the claim doesn't require the uses.

Now, let's compare that with what they're talking about.

Remember what it is that Palmaz actually invented. He invented a method of expanding a metal tube on a balloon and then implanting it as a stent. Deliver it by catheter and you implant it as a stent.

He invented the combination of putting the stent on a balloon. Okay? Agreed. He invented that.

What he didn't invent was simply having a tube that you could expand.

Remember I used this in the beginning. You have a surface with slots in it like this. You apply enough force. They open up. Okay?

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It would have been much harder for us to make a model that went around cylindrically out of wood. We had some things, but same principle. You apply enough force, slots open up.

There is simply nothing that is inventive about that. Ersek was claiming a special process, too. He didn't try to claim a slotted tube. And all of the recognition, you know, what's all the recognition that Dr. Palmaz gets?

Well, he gets recognition for his process of balloon expandable stent, putting the stent on the balloon, delivering it by catheter, blowing it up.

He gets recognition for the combination, but no one is recognizing him because he invented a metal tube with slots in it. Even he didn't say that he was the first to have a metal tube with slots in it or even elongated slots.

That is not an invention. That was something Dr. Ersek had ten years earlier and undoubtedly, at least in the medical field, undoubtedly for other reasons, other people had it.

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MR. BADENOCH (Continuing): What did Dr. Palmaz receive all his awards for? Same thing. The process of having a stent on a balloon and actually

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putting it in by a catheter and blowing it up and taking the balloon out, and so forth.

That's what he got his awards for.

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MR. BADENOCH (Continuing): Incidentally, I think counsel for plaintiff was suggesting that, yes, how, you know, was it somehow disrespectful for Dr. Snyder to refer to some of these award ceremonies at the party? And here's their exhibit, just to explain for a moment.

You have 7618?

I don't know if we can blow up these. I remember this. Here's Dr. Palmaz (indicating). Actually, the pictures, I think you can see all the glasses here.

There's nothing wrong with this, of course. He's entitled, absolutely, to celebrate his achievements, but there's also nothing wrong with Dr. Snyder referring to his award ceremonies as involving festivities. They obviously did.

What was the basis for all of the licenses and all of the money that was paid to Dr. Palmaz?

Again, if you go back, it's the same thing. He got awards for the process invention and the combination. He got -- he received money. Incidentally,

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as you've heard, he received money. Don't worry about Dr. Palmaz. He's fine.

He got awards for the combination with the balloon. He didn't get an award for inventing this (indicating), an expandable metal tube. And if you look at the claim, the word balloon is not in the claim anywhere. You'll have the claim in suit in your patent. The word coronary is not in there.

This claim is something, it has to be capable of use as an intraluminal graft and we'll show you that it is.

But the claim is to the metal tube. It's got the thin-walled tubular member and all those features.

What were the doctors that we heard so skeptical about? They weren't skeptical about applying force and doing this. Everybody understood that. What they were skeptical about was if you left metal in an artery, you would have thrombosis and clotting. That was, indeed, a problem.

And, in fact, it was, and it continued to be a problem because the doctors, what they did was they prescribed very harsh drug regimens, as you heard: Coumadin, also used as rat poison and so forth.

Yes, Dr. Palmaz had ideas on this, fine. But what actually changed the field was not Stress and

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Benestent. What changed the field was when Dr. Columbo, with ultrasound techniques, was able to establish and publish on this, and with his reputation, convinced the whole community they ought to be using higher-pressure balloons, implanting the stents differently and not using these drug regimens.

And when they were able to do that, that's when this business actually took off.

Now, as I mentioned, Claim 23 is on the tube. Let's just compare how similar that is to what Dr. Ersek came up with ten years earlier.

May I have the -- our position is going to be that, and I will explain the evidence to you on this, Claim 23, not Dr. Palmaz's process invention, not his combination of the balloon, but Claim 23 really is obvious over Ersek.

Why? I think we have a -- here's what's in the Palmaz patent. Here's a description of the method of delivering his balloon stent. Okay? Here's a description of the combination of the stent on the balloon. That's in Figures 3 and 4 and it's all described in the patent.

However, Claim 23 is on this (indicating), the slotted tube.

Now, Dr. Ersek also has a patent, ten years

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earlier, in which he's talking about a process. It's a different process. We admit that. He's talking about a method of expanding and implanting an Ersek device to hold a graft in the aortic artery during a surgery operation. Totally different process. And for that, he came up with his expandable metal tube (indicating), same kind of thing. We'll show you it has exactly the same features except a few are slightly different and modifying those is totally obvious.

Okay. So what happens is when you compare this with Claim 23, you see, the methods, these are different. They don't really overlap and we're not saying they do.

This is where we are in this case. Claim 23 is on this tube (indicating). And here's Ersek. He's got his tube. And when you look at the features of the claim, you're going to see that these are the same except for very, very minor differences, which don't matter. And that's why Claim 23 is obvious and invalid.

One more slide. Here, just to put it in perspective, this is Ersek's tube. He did it in 1970. The patent was published in 1972.

Here is Palmaz's first pictures in his monograph. This is in evidence. Here was his woven wire. Here's his slotted tube.

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If you look at -- these are practically identical here. When he went to the patent, he had a little bit more sophisticated slotted tube. Still, you have the same idea. Slots. You have elongated struts. You have a cylindrical surface. You have -- these things have a first and second diameter and so on, as we'll show.

Okay. I want to turn now to the infringement issue and talk specifically about why their case is off point.

Remember, this is the, really, the crux of it. When you talk about actually measuring how thick the wall surface is, as we say you should, the whole wall surface of the cylinder, we put in elaborate proof on that. Dr. Snyder explained in some detail how he took confocal laser measurements and how he took optical comparator measurements and how, why the variations in thickness work.

They have not answered that in terms of anything wrong with his measurements. They have not done any measurements themselves at all. They have no proof other than to try to shift the issue.

It's their burden to prove this and the wall surface thickness variations, they put in no proof on it at all. The reason is because they really don't have

the uniform spacing between slots as previously described, but also because the thickness of the wall surface or the thickness of the connecting members, elongate members and so on, is the same uniform thickness.

And so he said, Oh, those are equating, he says or, so they are equating the struts to the wall.

Look at what they're talking about there. They're talking about, as he agreed, I think he said this, they're talking about the preferred embodiment of Palmaz and the preferred embodiment is this. It is cut from a tube. It's cut from a cylinder. Perfect cylinder.

So if you cut it from a cylinder, you start with a perfect cylinder or tube here, you cut these slots out, each slot that remains -- I'm sorry, each strut that remains is going to be the same as the thickness of the wall.

So if you are talking about a tube, something cut from a tube, then, yes, they're the same, and that's what they are talking about here. That's not true if you are talking about something where the struts are twisted or whether you have parts that protrude out, like the NIR design. That's not what they told the Patent Office when they were talking about other things with twisted struts. They said quite the opposite, as we'll

see.

So what you need to be conscious of is, is there a variation in the thickness of the cylindrical wall? Not the strut. And is the variation more than a hundred percent?

That alone takes it out. If it's less than a hundred percent, is the variation important? Either one of those means it doesn't infringe.

I want to turn to validity. Let's go back, then, to the claim.

Why is this claim invalid? And keep in mind, we're not -- you know, I want to keep saying this. Dr. Palmaz, you know, his -- his memory is bad on dates when he did things and stuff like that, but he clearly invented something important here and he has clearly gotten a lot of well-deserved credit. No one is trying to question that. Our witnesses didn't question it. I don't question it. And he has been paid handsomely. Okay.

But what he invented was a stent that you put on a balloon, the combination on the balloon, and the process of delivering it on the balloon catheter and implanting it in the artery. That's what he invented and on that, everything is fine.

The problem is in this case -- we have a

limited case here. I should mention counsel was kind of implying at one point that BSC doesn't dispute anything other than substantially uniform thickness. There are other disputes. What's agreed is that for this case, and for your consideration, there's the one limitation, but what Dr. Palmaz did not invent was this (indicating), an expandable metal tube with the requirements of Claim 23. And that's why you have to find this claim invalid.

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MR. BADENOCH (Continuing): It's too broad compared to what Dr. Palmaz actually invented.

You can have a claim on the process. You can have a claim -- a method claim that says the steps of. That is what these method claims look like, steps of putting an expandable tube on a balloon catheter, delivering it inside the lumen to a remote site.

- - -

MR. BADENOCH (Continuing): Expanding it at the remote site. Deflating. That's fine. You can have that kind of claim. It's not this claim.

You can also have a claim that says putting a -- the stent in combination with the balloon, selling a combination. You can have that kind of claim. It's not this claim.

This claim basically reads on Ersek, with very, very minor details.

I think we can go through that fairly quickly.

Let's go back -- do you have the next slide here? I'm sorry. One more thing.

Remember the scheme here. I want to back up. And there's no dispute about the law on this. Both sides say the same thing.

Here's what you do. You determine the level of ordinary skill. You then determine the scope and content of the prior art. You then compare them to see what's different. You also look at secondary factors, like commercial success, recognition, that sort of th although when you look at those, remember, you've got to -- we're talking about Claim 23. The recognition and success for other inventions is not -- that's not

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that the asserted claim is invalid. Clear and convincing evidence is evidence that produces an abiding conviction that the truth of a factual contention is highly probable. Proof by clear and convincing evidence is a higher burden than proof by a preponderance of the evidence.

So what does that mean? You remember on our case to decide the wall thickness, all you need is the scales tipping to our side, where I think they do.

Their case, they've really got to put on a lot of evidence. They've got to produce an abiding conviction, an abiding conviction for you all that Dr. Palmaz's Claim 23 is obvious.

I think you'll find they're woefully short.

Next important point. If you find that the individual limitations of the claim are present in the prior art, then you must decide whether it would have been obvious to a person of ordinary skill to combine or modify them in the same manner as the asserted claim.

What does that mean? It means that we're talking about a combination claim, and you have not heard anyone say Dr. Palmaz didn't invent the catheter, Dr. Palmaz didn't invent balloon angioplasty and Dr. Palmaz didn't invent slotted tubes. What he invented was the unique combination of those three ideas in a way no one had ever thought of before. That's his invention. So

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what it's saying is, okay. Slots are there, tubes are there, angioplasty is there, catheter is there. The question is is there a reason to put them together, as Dr. Palmaz did. Is there a reason to combine.

And so you start, of course, it's fine to look at the patent. You have to do that. But a determination of obviousness cannot be based upon the hindsight combination of prior art. Hindsight. 20/20 hindsight. A lot easier in 2005 to look back and say something is obvious than it was in '85.

It's wrong to use the patent in suit as a guide through the maze of prior art. I think you can find that that is all that BSC is doing: Working backwards from the patent, as Mr. Badenoch more or less admitted, and I will show you in a minute.

The teachings of the prior art can only be combined if there's a reason. There's got to be a reason to combine them. So what you've got to do is think, no hindsight. Is there a reason? Is there a reason, for example, why anyone under the sun in 1985 would take Ersek and make it small and smooth and tiny and put it on a balloon and put it on the artery or is that something that's really ridiculous to imagine and only the product of a brilliant imagination of Julio Palmaz.

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What's the flip side of motivation combined? The flip side, which you are also required to consider, is whether the inventor proceeds contrary to the accepted wisdom. You're required to consider disbelief or skepticism towards the claimed invention. That's the flip side of motivation, to combine, and that's part of your analysis, too. And as you know, and as I will review, there was plenty of doubt about Dr. Palmaz's brilliant insight.

And, lastly, how are you figuring this out? How are you thinking about it?

It is not whether it would be obvious to you as a layman, to Judge Robinson, or to a genius. The question you have to decide is whether it would be obvious to one of ordinary skill. That's the question.

And the person of ordinary skill, you have two people working in combination: A doctor. Why? Because the doctor understands the problem of heart disease, and he's working with an engineer. Got five years experience in implantable devices.

Why the engineer? Well, he knows the advantages and the disadvantages of implantable devices and can help design. Okay. So these are two ordinary guys in 1985, thinking about solving the problem of balloon angioplasty.

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Now, so then we take a look at the claim. And, as I said a moment ago, as I will say again, Dr. Palmaz didn't invent the balloon. Dr. Palmaz didn't invent the catheter. Dr. Palmaz didn't invent the slotted tube. I hate to disappoint BSC. Dr. Ersek didn't invent the slotted tube either. There are lots of slotted tubes out there. The question is: Dr. Palmaz's combination. The question is: The balloon expandable, slotted tube stent invented by Dr. Palmaz that sits now in the Smithsonian. That unique combination of ideas is what's in Claim 23.

It has three elements, as we've reviewed before.

First, you've got to have a first diameter, including intraluminal delivery through the body passageway. That's Dotter's idea from 1969. And, as Dr. Snyder agreed, what that means is a catheter.

Got a second diameter. A second diameter has two important elements.

The first is the clever, clever idea, it's Dr. Palmaz's idea, of using a balloon controllably expand and deform a structure so it's just the right size.

Dr. Palmaz's brilliant insight requires a balloon, requires something internally, and Dr. Buller has told you that in 1985, the only thing that could

MR. DISKANT (Continuing): The next step is profound disappointment. Then we get this sobering second look and we say, it really does work, and here's where it works best.

Thank goodness, thank goodness that these pioneers of medicine pushed on, that Johnson & Johnson continued its investment, unlike SciMed and Boston, who had nothing to do with any of this.

1993. 1993 now. By this time, the Stress and Benestent studies is under way. Johnson & Johnson has made its investment. The results aren't out yet.

This is September 93. Dr. Bain, Dr. Kuntz, leaders of the medical community, they look at the Palmaz/Schatz stent. They look at atherectomy, the Roto-Rooter. They look at the laser, say I don't think these are going to work. Balloon angioplasty is likely to remain the workhorse, as late as the fall of '93.

What happened next? Two months later, the preliminary results of Stress and Benestent were published, reported at the American Cardiological meeting. Dr. Buller wrote the story and you saw it in evidence.

And then, and then, the summer of 1984, the final results. Final results in the lead two articles in

the nation's most important medical journal, the world's: Stress and Benestent. Dr. Buller, one of the participants. It works. The Palmaz/Schatz stent gives better results than angioplasty. Bam. FDA approval. One month later, Palmaz/Schatz goes on sale in the United States and now there's a frenzy of activity in the stent development industry.

And even Dr. Low began using the Palmaz/Schatz stent immediately.

Remember Dr. Fischell, our first witness? A cardiologist from Minnesota who helped design the second-generation BX Velocity. He got on the phone, began lobbying with J&J to be one of the first stents, fortunate to get their hand in the Palmaz/Schatz stent because it worked. Dr. Fischell could go home at night and not worry about his patient having a heart attack in the middle of the night.

Exciting times. Overcoming skepticism, overcoming doubt and percent veering.

What is Claim 23? Claim 23 is the slotted tube balloon expandable stent. It is Dr. Palmaz's invention. It describes every successful stent in the coronary market. Every one of them is a first diameter intraluminal delivery expanded by force, expands the lumen and has the characteristic longitudinal slots that

Dr. Palmaz realized would provide the great radial strength to support the vessel through two billion pulsations.

The slotted tube, slotted stainless steel expandable stent pioneered by Dr. Palmaz. It's the first balloon expandable stent based on Palmaz's stainless steel design.

Is there a competing idea in the marketplace? Yes. After Palmaz designed the slotted tube balloon expandable stent, after he invented the idea of the balloon expandable stent, Dr. Gianturco, who I will talk about a little bit later, came up with an entirely different idea. The coil stent was like a Slinky and it was very, very flexible, but it failed. It didn't have the strength. Dr. Buller told you it was tested and tried and used to be -- used in patients and it was inferior. The slotted tube design is a design that has stood the test of time. It is the design that has revolutionized cardiology.

The coil stent produced worse results and from a marketing perspective, Mr. Croce told you what happened after it was published, that it was a lousy stent? Doctors started sending the product back. They pretty much stopped selling it. The coil stent has just disappeared.

So what's their case? What's their attack on Dr. Palmaz's work? Ersek. You can't see this one either. I'm sorry. Ersek. A device used in open-heart surgery, a device that's completely antithetical to everything that Dr. Palmaz was trying to do. The device was entirely antithetical to his entire profession, to Dotter, Gruntzig and Palmaz.

Why in the world would anyone take Ersek and put it on the tip of a balloon? I asked Dr. Snyder. It's for surgery?

Yes, it was for surgery.

That's exactly what Dr. Palmaz was trying to avoid; correct?

Yes.

Well, what is their case? What point are they making? I don't get them.

When you get the instructions, look at the prior art, one of the things you're supposed to think about is what prior art was reasonably pertinent? The problem that the inventor was facing.

Why in the world would someone who's trying to improve angioplasty be interested in a device used in conventional open surgery? And what is their description of Ersek? How far from reality have they gone to try to persuade you that Dr. Palmaz's work is obvious?

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I think Boston and SciMed -- well, they're desperate. They're making things up.

Dr. Snyder told you again and again and again. It's not a stapler, doesn't say it's a stapler, says nothing about stapler, says nothing about sharp, says nothing about penetrate. Never, never, never, never.

Well, gee, how to figure if that is true or not. You can read the patent. You can rely on what Dr. Buller told you. But you could also think, what does Ersek think he invented? Here's what his resume says about the '744 patent. It's a valve seat, a new staple-like device to allow for the rapid installation of prosthetic and transplanted heart valves.

A staple-like device. What is Dr. Snyder talking about? They questioned him about not just Dr. Buller's opinions, not just Dr. Andros' opinions. Richard Heuser, another distinguished surgeon, one of the stress pioneers.

And I questioned him. What about this? Dr. Heuser, do you agree with Dr. Ersek's description of his device as a staple-like device?

I agree with his description of his device, yes. It's a staple-like device. Who thinks it is? Well, Dr. Buller and Dr. Andros, Dr. Heuser and Dr. Ersek.

Who thinks it isn't? Dr. Snyder.

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Well, why don't you take a look at the patent. The patent is very short. I know reading technical documents isn't a lot of fun, but it's for use in a surgery. It's just simply what it says. That's what is true. That's what -- you'll see this on the first page. The transplant situs during surgery. That's where it's for use. You cut open the patient's chest, you work on his heart valve. You transplant an aorta. This is major invasive stuff. This isn't what Dr. Palmaz was all about.

How does it work? Well, it's replacing suturing. You know, instead of sewing, stapling. Sewing, stapling. That's all it is. That's why it has ribbon-like portions that create multiple projecting edges that imbed themselves into the tissue. It staples. One click, one bolt. Single stroke of the expanding tool. Bang. I'm sorry, I didn't mean to say bang, George, but guess what? It's how it works.

So let's see what that gun reminds us of. That wasn't my question, Dr. Snyder. Let's try my question. It looks just like the device, the kind of structures that doctors use today to deliver staples? Yes or no?

Yes.

All right. So what have they told you about

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Ersek? They showed you this demonstrative and I must say, it was obvious so silly that Mr. Badenoch needed to talk about in his opening. Yes, I was going to comment on it. I was going to comment on it for two reasons.

One, remember the part about not using hindsight? This is Dr. Palmaz's publication from years later and, yes, this is precise copy of Dr. Palmaz's design. Hindsight, maybe? I think so. Could be. Maybe. But it's also entirely wrong. It takes a second to figure out why.

Do you see the metal? You can see all the metal protruding. It's nestled snug, like in a bed. That's Palmaz's idea. That's not Ersek's idea.

So you see all the metal. You see the double thicknesses there and there and there and there and there and there. It's not cutting into the skin at all. Is that what Ersek had in mind or is this just a figment of Dr. Snyder's imagination?

Well, you can read the words of -- that Dr. Ersek said. That might help.

Because of the twisted relation of the ribbon-like portions, very little metal is actually in contact with the bloodstream. It goes right in, into the vessel lining. Very little metal is in contact with the bloodstream.

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What's wrong with this picture? What's wrong with the picture is lots of metal is in contact with the bloodstream because they have not inserted it all the way in this illustration.

How do you know that we're right and they're wrong? First, that's what the words say. The words do matter. And here's what Dr. Buller said: He means something he's describing the words, said Dr. Buller. He means that when you expand his device, there is very little of the metal left in contact with the blood and the only way that is possible is if it is penetrated into the wall.

This isn't what it looks like. This is what Palmaz does. This is using hindsight to turn Ersek into Palmaz. And here's the killer. A description from Dr. Ersek's resume that we read. The first sentence was about being a staple-like device. Here's what the second sentence said: This device is incorporated into the wall of the housing vessel or heart and thus never comes in contact with the passing blood. It's a stapler. That's not what it looks like. That's just using hindsight to make Ersek look like Palmaz.

The bottom line, no one has described Ersek as not a stapler except Dr. Snyder. You decide whether to believe him. You decide whether his testimony was

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clear and convincing and gained a moral certainty and abiding conviction that he was steering you right.

We do know one thing. The United States Patent Office doesn't agree with Dr. Snyder. Claim 23 has been approved twice by the U.S. Patent Office. Claim 23 was issued in 1988. It has been sitting in Dr. Palmaz's patent ever since 1988, ten years before Boston Scientific and SciMed began using his invention and selling the NIR stent in the United States.

And then, patentability confirmed, 1998, ten years later.

And what did the Patent Office say? Well, it's actually pretty ringing, but they are dealing with an important invention. And they say the plain and simple truth. All that stuff that Mr. Badenoch showed you before, they say it was rejected. Why was it rejected? Because, as the opening video told you, at the beginning of the patent process, more frequently there's a rejection. This is their technical back and forth in the patent system. More frequently, there's a rejection. And it goes on until the final issue, until the final issue tells you where the U.S. Patent Office winds up.

And the final issue is the initial rejection, none of those grounds are right. None of them are right.

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No combination. No other combination of these references can be used to properly reject any of the claims.

In addition to these references, all, all of the other references have been carefully considered. None, look at that underlining, Michael Thaler, the patent examiner, the U.S. Patent and Trademark Office knew he was dealing with something very important. None of the references of record, whether considered separately or in any combination, can be used to properly reject any of the claims as they now stand.

And what references were those? Well, the Patent Office thought Dr. Palmaz's Claim 23, the combination of angioplasties and catheters in a slotted tube, a balloon expandable slotted tube stent wasn't obvious in light of Dotter and it wasn't obvious in light of Gruntzig and it wasn't obvious in light of the self-expanding stents. It wasn't obvious against many, many other patents, including the Ersek staple. That's what the Patent Office thought. They persuaded you clearly and convincingly they were wrong.

Very quickly, the marketplace of ideas. Excuse me. The Palmaz abstract. This tiny little paragraph, it doesn't tell you. That's the problem. This is not Dr. Palmaz's work. It's a few sentences in an advertisement. And I went through this with Dr. Snyder and he agreed. It didn't say anything explicitly about any of the important ideas that Palmaz had. It doesn't say anything about controllable expansion. It doesn't say anything about plastic deformation. It doesn't say anything about a tubular member with substantially uniform wall thickness. It doesn't say anything about longitudinal slots. I forgot to put on the slide, but it's true, it also doesn't say anything about smooth either.

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It does not tell you anything. It's not an important part of the prior art. It's just another self-expanding stent by all apparent purposes.

Okay. Let me tell you just a little bit about the exciting ideas that were going on and I will do it quickly because I'm running out of time. But this was a very exciting race back in the 1980s. Thank goodness for it. This is what science is all about.

Palmaz, 1984, first public disclosure of his balloon expandable stent up against Gianturco, a great man, a great scientist. He was invested in the Z stents. And there they were, back to back, competing against each other in the marketplace of scientific ideas.

And then, 1985, Palmaz press his slotted tube balloon expandable stent. And what happens to Gianturco? What happens to good science? It moved forward incrementally. Palmaz has now disclosed the slotted tube stent. Gianturco gives up on Z stents and moves on to balloon expandable stents himself. He designs the coil stent. It didn't work. That's too bad. At least it didn't succeed, but that's what science is about. It's exciting.

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Meanwhile, on our side of the ledger over here, Palmaz perseveres. First Palmaz slotted tube stent sold, 1991. Stress, Benestent, and today.

Dr. Richter, who wasn't big on praise, did say, Gianturco and Palmaz are definitely pioneers who enabled the whole field. That's true. There's also a difference. Dr. Gianturco, fine, brilliant scientist though he was, first chased self-expanding stents and then the coil stent.

Dr. Palmaz was the giant who had the vision that was right.

And I'm an admirer of Gianturco. These were exciting times. These were two great men battling each other in the intellectual marketplace to see who could improve the lives of all of us.

- - -

MR. DISKANT (Continuing): That happened thanks to Dr. Palmaz. You bet. You bet. Think about

Page 1352

THE COURT (Continuing): Plurality of slots. More than one slot. A slot is a long and narrow opening or groove, an opening whose length is substantially greater than its width.

The claim requires slots in the tubular members that run substantially parallel to the longitudinal axis.

Slots formed therein. The stent must be constructed to contain a plurality of slots in its wall surface.

Smooth surface. The outside of the wall surface of the unexpanded tubular member, has a continuously even surface, without roughness, points, bumps or ridges, especially to the touch.

A patent owner may enforce its right to exclude others from making, using, offering to sell or selling a patented invention within the United States by filing a lawsuit for patent infringement. Here, Cordis has alleged that the accused stent infringes the asserted claim. Cordis has the burden of proving by a preponderance of the evidence that Boston Scientific has infringed the asserted claim.

Patent law provides that any person or business entity which makes, uses, offers to sell, sells

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or imports without the patent owner's permission any product or method legally protected by at least one valid claim of a patent in the United States before the patent expires infringes the patent.

A company may infringe a patent without knowledge that what it is doing is an infringement of the patent. A company may also infringe even though in good faith it believes that what it is doing is not an infringement of any patent. Knowledge or intent to infringe is not relevant.

For an accused product to infringe an asserted claim, the subject matter of the claim must be found in the accused product. In other words, an asserted claim is infringed if the accused product includes each and every limitation of the claim. Infringement must be determined by comparing the accused product to the asserted claim. If the accused product omits any single limitation recited in the asserted claim, that product does not infringe that claim.

In this case, Cordis contends that the wall of the tubular member of the accused stent literally meets the substantially uniform thickness limitation of the asserted claim. The Court has defined this limitation on Pages 19 to 20. In order for you to

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determine whether the wall of the tubular member of the accused stent meets the substantially uniform thickness limitation of the asserted claim, you must determine whether the physical structure of the tubular member of the accused stent precisely meets or satisfies the claim language as construed by the Court.

Remember the question is whether the substantially uniform thickness limitation is met and not whether the accused stent is similar or even identical to a stent made by Cordis. Accordingly, you must be certain to compare the accused stent with the substantially uniform thickness limitation and not with any stent made by Cordis.

Keep in mind as well that, so long as the wall of the tubular member of the accused stent satisfies the substantially uniform thickness limitation of the asserted claim, that asserted claim is infringed by the accused stent. Even if the stent was independently developed, patented or represents an improvement or over the invention described in the asserted claim.

Therefore, if you find that the wall of the tubular member of the accused stent has a substantially uniform thickness, you must return a verdict of infringement as to the asserted claim.

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If you do not find that the wall of the tubular member of the accused stent has a substantially uniform thickness, you must return a verdict of noninfringement as to the asserted claim.

Boston Scientific contends that the asserted claim is invalid because it is obvious.

In considering Boston Scientific's assertions of invalidity, the Court instructs you that the law presumes each claim to be valid. In addition, each claim of the patent is presumed valid independently of every other claim in the patent. It is Boston Scientific's burden to prove invalidity by clear and convincing evidence.

In order to be patentable, an invention must not be obvious to a person of ordinary skill in the art at the time the invention was made.

The issue is not whether the claimed invention would be obvious to you as a layman or to me as a Judge or to a genius in the art, but whether it would have been obvious to one of ordinary skill in the art at the time it was made without the teachings of the patent in suit.

In determining obviousness or nonobviousness of the claimed subject matter of the asserted claim, the following steps should be taken by you.

Exhibit K

- VOLUME B -
IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION, : CIVIL ACTION
Plaintiff :
:
vs. :
:
MEDTRONIC AVE, INC., BOSTON :
SCIENTIFIC CORPORATION and :
SCIMED LIFE SYSTEMS, INC., :
Defendants : NO. 97-550 (SLR)

BOSTON SCIENTIFIC CORPORATION : CIVIL ACTION
and SCIMED LIFE SYSTEMS, INC., :
Plaintiffs :
:
vs. :
:
ETHICON, INC., CORDIS CORP. :
and JOHNSON & JOHNSON :
INTERVENTIONAL SYSTEMS CO., :
Defendants : NO. 98-19 (SLR)

CORDIS CORPORATION, : CIVIL ACTION
Plaintiff :
:
vs. :
:
MEDTRONIC AVE, INC., BOSTON :
SCIENTIFIC CORPORATION and :
SCIMED LIFE SYSTEMS, INC., :
Defendants : NO. 98-197 (SLR)

Wilmington, Delaware
Friday, March 18, 2005
9:08 o'clock, a.m.

BEFORE: HONORABLE SUE L. ROBINSON, Chief Judge, and a jury

Valerie J. Gunning and
Leonard A. Dibbs,
Official Court Reporters

APPEARANCES:

ASHBY & GEDDES
BY: STEVEN J. BALICK, ESQ.

-and-

PATTERSON, BELKNAP, WEBB & TYLER LLP
BY: GREGORY L. DISKANT, ESQ.,
EUGENE M. GELERNTER, ESQ.,
WILLIAM F. CAVANAUGH, JR., ESQ.,
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MARK CHAPMAN, ESQ. and
WALTER HANLEY, ESQ.
(New York, New York)

Counsel for Boston Scientific
Corporation

- - -

PROCEEDINGS

(Proceedings commenced at 9:08 a.m.)

THE COURT: I understand we have issues.

MR. BADENOCH: Good morning, your Honor.

THE COURT: Good morning.

MR. BADENOCH: To do this before the jury comes in, I just -- I understand of course the Court's ruling yesterday and we respect that, but I did for our record want to offer the exhibits that I referred to and I understand counsel is going to object.

And for the record, I will just recite what those were. They are Plaintiff's Exhibit -- I had them on a list here. It's Plaintiff's Exhibits 3642, 43, 44 and 45, Defendants' Exhibit 4507, Plaintiff's Exhibit 1137 and 1126.

And then I have a proffer of one more exhibit, Defendants' Exhibit 4585, which is one more letter that I would have concluded that line with yesterday, although I understand the Court has asked us to stop that line of examination. So we respect that, but I just want to make the proffer on the record.

THE COURT: All right.

MR. BADENOCH: And just for the record, our position is that that does relate to credibility consistent with the Court's prior ruling because he gave a story of conception and we feel it's inconsistent with his prior --

THE COURT: Right. And I think the discussion we had in our -- when we pretried this case was that the defendants would be given some leeway, but there would be a line as always because conception is not at issue and I just -- in my belief, you crossed that line.

But, in any event, I don't know what any of these exhibits are, so I suppose we need to go through them to see what, if anything, should be admitted or not.

MR. DISKANT: I object to all of them, your Honor. They are basically a collection of documents. To the extent they had -- I would look at it this way. I think the examination made points that the documents make. I think it went way over the line. I think adding the exhibits to that would compound the damage. They are -- the documents themselves are utterly irrelevant to any issue in the case. They're receipts from balloon catheters and they're grant applications

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A. Absolutely, it does. It is -- it is a very uniform structure. We've looked at very careful measurements done by Boston Scientific's own engineers and experts and I just wanted you to see a real device so you have some idea as to the scale of the device we're talking about that I use.
Q. All right.
(Pause.)
BY MR. DISKANT:
Q. All right, Dr. Buller.
Now I would like to turn to the allegation by Boston Scientific that Claim 23 is obvious.
Have you considered the question?
A. Yes, I have.
Q. And did I give you standard by which to consider it?
A. Yes.
Q. Let's take a look at the standards.
The obviousness analysis: One, the scope and content of the prior art. What did you understand you were supposed to do, the generality with respect to that issue?
A. You have to put yourself back into the time frame of Dr. Palmaz's invention. So back to 1985 time frame. And you have to look at the -- the whole content of the

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prior art. You have to look at all the ideas and things that were available in order to look and see if this was obvious, this invention of Dr. Palmaz, without using hindsight, without putting yourself at today. We know what it is and we know it works. You've got to try and avoid that.
Q. Then you have considered differences between the claim and the prior art. As a generality, what did you understand that instruction to mean?
A. You looks at the careful words of the claim and you have the benefit of the Court's claim construction, meaning of the claim elements, and you compare that with all of the information in the prior art, this very large amount of information.
Q. Do you look at the claim as a whole?
A. The claim as a whole.
Q. And why do you do that?
A. Well, because Dr. Palmaz's invention is this unique combination of this non-surgical deformable slotted tube structure. I mean, Dr. Palmaz didn't invent slots. Dr. Palmaz didn't invent balloons. Dr. Palmaz didn't invent tubes. Dr. Palmaz didn't invent a smooth surface, as on my desk in the courtroom.
I mean, you if take any of the individual bits, of course, he didn't invent those tiny individual

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words. What Dr. Palmaz has invented was this unique combination of these things to treat patients without needing a major surgical procedure, to intraluminally deliver it.
Q. Then you consider the level of ordinary skill in the pertinent art at the time of the invention.
What did you understand that to mean?
A. This is looking at a person back in that time frame, what that person would be or the people that that person would be, because it may well be, and it's certainly my opinion, that it would be a combination of a doctor treating patients with vascular disease and an engineer with a certain experience with, in terms of medical device.
Q. The ordinary person -- does the ordinary person presume to understand all of the pertinent prior art?
A. The person would have access to all of the prior art, certainly would be able to look at everything to see if it rendered Dr. Palmaz's invention obvious. Anyone would have thought of it. Anyone with these skills would have thought of it.
Q. Lastly, objective factors such as commercial success, long-felt but unresolved need, failure of others to solve the problem.
What's that factor as you understood it?

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A. This is a very important way to try and avoid hindsight. The trouble is with a lot of brilliant inventions, years later people can say, it's obvious. I would have thought of that. So one needs to go back in time and actually see what people thought at that time, back in the mid, late eighties, early nineties. Did people think it was obvious? Did they have concerns that it actually might not work? Did the same people that are being accused of infringement actually say, this is kind of a clever idea?
All of those factors help to avoid hindsight, because you are going back to documentation much closer to the time of the invention.
Q. Okay. Let's take a look now again at the claims we looked at briefly before.
And I prepared this slide breaking this claim into components that understand the combination that Dr. Palmaz claimed?
A. Yes.
Q. It talks about a tubular member having a first diameter which permits intraluminal delivery of the tubular member into a body passageway having a lumen.
What does that mean to you? What do you understand Dr. Palmaz to be disclosing?
A. This teaching is to do with avoiding surgery. This

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is -- this very important phrase, intraluminal delivery. This is avoiding cutting open a patient, removing parts of the patient, incising. This is treating the patient through the passageways of the body. You are actually going for intraluminal delivery as opposed to major surgery, and this is teaching that you need the device to have a first diameter, i.e., a small diameter, to allow you to intraluminally deliver it.

It's not talking about a big thing that you are going to force in at the time of an operation.

Q. Now, in 1985, how was intraluminal delivery achieved?

A. By catheters. It had been taught by Dotter back in '69, this concept of trying to do a procedure. Dotter had some ideas, but certainly not the idea like the balloon or Dr. Palmaz's idea. But he first came up with the idea of trying to treat patients without surgery, through the lumen, by intraluminal delivery.

Q. Is that what I'm holding? Is this the catheter?

A. That is a catheter. The stent is on the end of the catheter. That is an example. There are many different catheters, but that's an example of a catheter to allow you to do a procedure without opening the patient up, cutting them up, cutting bits out.

Q. Even today, is there any other way to achieve

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intraluminal delivery other than catheter?

A. No. In real terms, there isn't. We -- we use some form of catheter. For very much larger ones, we call other names like endoscopes and things. You can do things inside the digestive tract. Essentially, they are flexible devices to allow you to work down through body passageways.

Q. Is the catheter Dr. Palmaz's invention?

A. No. Catheters were known about and used, mainly in diagnosis. With Gruntzig, with balloons on the end. But nobody prior to Dr. Palmaz had come up with the idea of his slotted tube expandable, controllable, deformable device.

Q. All right. Let's look at the next element. I will just read the first paragraph here.

The tubular member having a second, expanded and deformed diameter, upon the application from the interior of the tubular member of a radially, outwardly, extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member.

First, what is being disclosed in what I've just read?

A. This -- this is the plastic deformation, the bending to get from the first diameter to the second diameter, so

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the plastic deformation is this deformed diameter. It is being bent to open it up. And this is controllable. One can choose what second diameter one goes to and stops at by adjusting the pressure in the balloon.

For instance.

Q. In 1985, how could one of skill in the art combine intraluminal delivery with controllable and deformed expansion inside the body?

A. I think the only way in 1985 was with a balloon catheter, as Dr. Palmaz's preferred -- preferred embodiment, was using a balloon, I think that's the only way you could do it at that time. I think that really remains true for all intents and purposes today. It is still the only way that we can plastically deform with such precision inside the body on a balloon catheter.

Q. Now, whose invention was the balloon, angioplasty balloon?

A. The current day sort of angioplasty is Andreus Gruntzig from 1977. He invented the refinement of balloons that allowed us to do angioplasty inside coronary arteries and in other blood vessels of the body.

Q. That's not Dr. Palmaz's invention?

A. No. And Dr. Palmaz in his patent clearly teaches that that is known. He was adding to this wealth of knowledge about non-surgical intraluminal delivery and

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about balloons that Gruntzig had made such important contribution to.

Q. Okay. The next phrase reads, whereby the tubular member may be expanded and deformed to expand the lumen of the body passageway.

What is Dr. Palmaz talking about?

A. Well, he's talking about the fact that this plastic deformation, this deformed structure in the second diameter, will be used to expand the lumen of the body passageway.

So the invention is to use it to open up to expand the lumen of a body passageway. It isn't being put there for no reason. It's being put there to expand the lumen of a body passageway. That's to treat an area of narrowing or where narrowing is likely to occur.

Q. Is this limited to the coronary arteries?

A. No.

Q. Does it include the coronary arteries?

A. Completely, this includes the coronary arteries. Dr. Palmaz's main example of his invention was the coronary artery and specifically the left main coronary artery. It's not limited to the coronary artery. Dr. Palmaz wanted his invention to be usable in the coronary artery and that's very clear in the patent.

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stent.
Q. He notes also, the following year, Palmaz published the data that provided a unique and accurate insight into the problems that would torment stent implantation for the subsequent decade.
What's that a reference to?
A. This is a reference to the problems with thrombosis, anticoagulation, all of the sort of problems that we addressed over the years after Dr. Palmaz's invention.
Q. Is that the doubts that the scientific community had about stenting?
A. This is to do with some of the doubts. I mean there were other doubts such as fractures, metal fatigue, the things that I talked about. There were many different reasons for doubt.
Q. Doctor, let's look at PX-3810. That's from a book on intraluminal stenting by Sigwart, which I offer.
MR. BADENOCH: No objection.
DEPUTY CLERK: So marked.
*** (Plaintiff's Exhibit No. 3810 was received into evidence.)
BY MR. DISKANT:
Q. Who's Ulrich Sigwart?
A. Another famous interventional cardiologist from

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Europe. He's one of my past colleagues. He and I worked together in the early nineties at a hospital in London.
Q. If we can just pull up this paragraph right here. Thank you.
The first balloon expandable stent was based on Palmaz's stainless steel slotted tube design.
Is Sigwart giving credit to Palmaz for the stainless steel slotted tube design?
A. Yes, he is. Here, he's clearly giving credit for the slotted tube design, the design which is this very important way that all leading stents now use, that all the main market leaders use, this slotted tube design.
Q. Sigwart also notes, meanwhile, another balloon expandable stent, Gianturco's interdigitating coil design, was tested in animals. This stent was designed for the treatment of angioplasty complications.
Was there competition with Dr. Palmaz in the ideas of balloon expandable stent after his invention was made?
A. Yes. After Dr. Palmaz invented balloon expandable stents, other people came up with other designs. One of the designs was not to use -- to use coil structures. This didn't have the longitudinal slots. It failed in the marketplace. It didn't give enough support. It was

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tested and tried and used it patients. It was shown to be inferior. In fact, the makers of it withdrew it.
Q. Now let me draw your attention to PX-277, coronary stenting by Kutrik and Serruys. It's in evidence. I would like to direct your attention to Page 4.
The idea of a balloon mounted stent for simultaneous dilation and stent delivery was introduced by Palmaz and colleagues. Is Kutrik and Serruys giving Dr. Palmaz credit for his ideas?
A. Yes.
Q. Let me look at 3801, which I offer, the interventional cardiovascular medicine text, chapter.
MR. BADENOCH: No objection.
*** (Plaintiff's Exhibit No. 3801 was received into evidence.)
BY MR. DISKANT:
Q. This is by Roubin, et al. Who's Roubin?
A. Gary Roubin is an American interventional cardiologist. He's one of the designers of a particular type of coil balloon expandable stent called the Gianturco/Roubin coil stent.
Q. That's the design that eventually failed in the marketplace?
A. Yes. Eventually it failed.
Q. Let's see what Roubin says.

Page

The slotted stainless steel expandable stent, pioneered by Dr. Julio Palmaz, was initially reported in 1986.
Is Roubin giving Dr. Palmaz credit for his work?
A. Yes, he is, for the slotted stainless steel expandable stent.
Q. Okay. So let's turn to the obviousness case that Boston Scientific wishes to raise.
Mr. Badenoch, in his opening remarks to the jury, talked about the so-called Ersek device.
Are you familiar with the Ersek patent?
A. Yes.
Q. PX-95 in your book, and I offer it, if it's not in already.
MR. BADENOCH: It's already in evidence.
MR. DISKANT: It's already in evidence.
MR. DISKANT: Can we pull up the cover of Ersek?
BY MR. DISKANT:
Q. What's Ersek?
A. Ersek, this is -- this is a patent. This is an invention. This is a surgical device.
Dr. Ersek had an idea for a way of speeding up a surgeon's sutures, and he designed what one could

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fairly call a stapling device, so when you are doing a major operation, instead of a surgeon having to set to and sew the end of a graft you're putting in or heart valve you're putting in to the tissues of the body, you can use a device which will speed the process up and essentially staple the graft of the heart valve into place.

This is a surgical device to be used in a major surgical operation with a patient opened up. This had nothing to do with intraluminal delivery, the avoidance of surgery, the avoidance of excising, removing or any of the other features.

Q. Was the Ersek device ever sold as a commercial product?

A. I don't believe so.

Q. You prepared some slides walking through the Ersek patent to explain to the jury what it's about?

A. Yes.

Q. Let's take a look.

Is the abstract of the Ersek patent, and it says, the assembly may be rapidly introduced into the transplant situs during surgery.

What is this thing?

A. You misspoke. It's transplant situs.

Q. Sorry.

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A. A transplant is what it says: You are taking something out of the body and you are putting something in place. And Dr. Ersek taught that his device was to use in surgery, as this clearly says during surgery, into a transplant situs. This is where you may be replacing a whole part of a major body passageway or a heart valve, for instance, where you take one out and you put a new one in. This is a surgical stapling device to replace the surgeon's sutures.

Q. Does this have anything to do with the idea that Dr. Palmaz has combined the --

A. This has nothing to do with Dr. Palmaz's invention. This is in a completely different art. This is a way to speed up major surgery. This is not to avoid surgery in any shape or form.

Q. Let's look at the next slide. I think you mentioned -- let me read it. According to the prior art, artificial heart valves are installed by the careful placing of a plurality of stitches around the rim of tissue that will house the valve. The process takes 30 to 45 minutes in the best hands and from an hour to an hour and a half in the less than best. Valve installation takes place while the patient is on an artificial heart/lung machine and every minute is very important.

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What is Ersek talking about?

A. He's talking about the problem with major operations, is that speed of the operation is often dependent upon placing very accurately and very carefully and very skillfully a large number of stitches. And Dr. Ersek came up with a device to try and speed this process up, where the device, that by virtue of having outward projections, could be used to staple the heart valve or a graft in place in the body, and thereby speed up the whole operation, and thereby hopefully make it a little less long and there by a little safer.

Q. The patient is on an artificial heart/lung machine. Has the patient's chest been open?

A. Completely. This is major heart surgery that he's talking about here. The patient's chest has been opened. Their circulation has been put on a machine. Dr. Fischell spoke about it briefly. You have to stop their heart to operate on them. You plug in very large tubes which drain blood out of the body and put oxygen into it and pump it into pressure back into the body through another tube. The heart stops so the surgeon can start the sewing. This is major open-heart surgery.

Q. Does this have anything to do with the pioneering work of Dotter, Gruntzig and Palmaz?

A. It has nothing to do -- it has nothing whatsoever.

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This is in the sphere of major surgery. This is what Dotter, Gruntzig and Palmaz were trying to avoid. This is the antithesis of what they were doing.

Q. Now, let's go to the next slide.

The device of the present invention permits instant and positive fixation of heart valves, vessel grafts and other prosthetic members. The valve and its skirt composed of the sleeve is assembled on an expanding tool device. This assembly can be quickly and easily forced into place and the tubular sleeve expanded to hold the valve or other member in place.

How was the Ersek device inserted into the body?

A. Well, the Ersek device is not used on its own, never used on its own. It's used to put something else into the body, so it's used to put a valve in or to put a graft, a piece of tubing into the body, to replace something else, or to replace the function of something else.

And it is put in on a device, and up here, this is straight from the patent. This is Dr. Ersek's preferred way of putting it in this gun device. One would mount the stapling ring essentially on the end with the graft, the heart valve, whatever you were putting in and use this to put it in place with the patient opened

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up on the table, on the operating table.
This is a surgical device.
Q. Give a sense of scale. What's the diameter of a typical heart valve?
A. An inch, roughly speaking.
Q. You're talking about an inch. And what's the size of the gun?
A. It will be an inch. The reason why Dr. Ersek is saying forced into place, he teaches you need the device, his ring structure, to fix it in place, to avoid stitching. Need to be the same size as whatever you're replacing. And that's why it's forced into place. It has to match in size the area that you are operating on.
Q. All right. What's the size of the expanding tool if you are expanding a one-inch Ersek sleeve for a heart valve?
A. It will be very close to the one inch.
Q. No. The expander tool I'm asking about, Doctor. How big is the gun? How big is the gun?
A. Big.
Q. Bigger than this?
A. If this is an inch across here, then you get an idea of the scale of his preferred way of expanding it. This is his preferred way. This device will be a foot, 18 inches long, and it is a gun.

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Q. Okay. Let's go to the next slide.
The ribbon-like portions of the sleeve extend angularly relative to the perimeter of the sleeve providing a multitude of narrow projecting edges which imbed themselves into the tissue wall upon expansion of the sleeve.
What is he talking about? What is -- how does this device work?
A. This is what I would characterize as the staples. Dr. Ersek's invention has a multitude of narrow projecting edges and he shows these in any of his devices in cross-section. This is a cross-section and this shows a sort of saw-tooth appearance and these are the multitude of narrow projecting edges, which act as a stapler. These join together whatever you are putting into the body with where you are pointing it.
So to join a graft to a vessel, to join a heart valve to the transplant site, where you've removed a heart valve from.
Q. Okay. The next slide, please.
The new valve housed in the expandable sleeve is then placed in position and the sleeve is expanded in one stroke of the expanding tool.
What is he telling you?
A. This is Dr. Ersek explaining how it works, and by

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virtue of this explanation, you can see that if it worked, it would potentially be very quick. He has the idea that you have on the end of his gun mounted what you are trying to put in in the surgical operation, and you force it into place and then you pull the trigger, essentially, and he's saying that one stroke would put it in place, so you force it in and then, bang, and you've put it in place.
Q. One more slide, please.
The sleeve may be easily expanded by about 50 percent beyond its original diameter. The sleeves are formed to be a size appropriate for the implant being made.
What is he saying about how big the thing should be?
A. First of all, he's talking about making his fixation sleeve, his fixation device. He's saying you form it in a particular way and you can then adjust the size of it by up to 50 percent after you've made it into, if you like, a fixation ring, a fixation tube. But then it has to be the right -- he says the sleeves are formed to be appropriate size for the implant being made. He's saying by the time you move it, it has to match. This is why it has to be forced into place at the operation.

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He even teaches you have to get hold of the end of the -- of part of the body you're putting it into with little tie sutures, if you like, or pinchers to help you force it into place.
Q. Is such a device appropriate for intraluminal delivery as Dotter and Gruntzig and Palmaz taught?
A. It has nothing to do with intraluminal delivery. This is a surgical operative tool to try and replace a surgeon's sutures. I personally don't believe it would work. I don't believe it has ever been made. I don't believe it has ever been used to join two things together.
MR. DISKANT: Your Honor, this might be a good time to break.
THE COURT: Good. We'll take our 15-minute afternoon break.
(At this point the jury was excused for a short recess.)
(Short recess taken.)
- - -

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(Court resumed after the recess, and the following occurred without the presence of the jury.)

MR. DISKANT: Judge, before the jury comes in, I want to let you know there's a dispute. They wish to call a patent law expert who's objected to under the local rules. I don't think it need to be addressed this second.

THE COURT: I assume it's not going to happen this afternoon.

MR. BADENOCH: It's not this afternoon, your Honor.

THE COURT: Good. Let's bring the jury in.

(At this point the jury entered the courtroom and took their seats in the box.)

THE COURT: Mr. Diskant?

MR. DISKANT: Thank you, your Honor.

BY MR. DISKANT:

Q. Dr. Buller, have you prepared a series of slides showing the differences between the Ersek device and Dr. Palmaz's Claim 23?

A. Yes.

Q. Let's go through them.

First, an expandable intraluminal vascular

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graft. Is the Ersek device such a device?

A. No.

Q. Why not?

A. It is not -- it is not expandable in the sense that you can rcpsnfd the whole length of it. It is not intraluminal in the sense that intraluminal non-surgical delivery. It is a device to be used in surgery, to fix something else in place. It is not even used on its own. It is used to put in a heart valve or something else, which is a graft, typically a Dacron tube, a material tube.

Q. The next slide requires a wall surface which must be enclosed in a common cylindrical plane. Does that describe Ersek?

A. No. Ersek does not have a wall surface in a common cylindrical plane. As you can see on the cross-section of Figure 5 of Dr. Ersek's patent, it has a saw-tooth cross-section, and it is not lying on a common cylindrical plane.

Q. The next element, please. Requires the substantially uniform thickness that we've been talking about. A wall that varies in thickness by as much as 100 percent cannot be of substantially uniform thickness.

Does that describe Ersek?

A. Ersek has a variation in wall systematically all

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around it, all of a hundred percent. It is made from metal, which has been stretched to create the outward edges. On this you can see the thickness where it's in dark is essentially double the thickness where it is shown as light.

Q. The next element, please.

Whereas a first diameter which permits intraluminal delivery of the tubular member into a body passageway having a lumen.

Does that describe Ersek?

A. No. It does not describe Ersek.

Intraluminal delivery is this non-surgical term. It's used in the art for delivery along a body passageway avoiding surgery. Ersek is the antithesis of that. Ersek is a surgical device to use in an open operation to replace the surgeon's sutures, to join something together other than the device it.

Q. Next slide, please.

Requires a controllably -- a second, expanded and deformed diameter, upon the application of radially outwardly extending force, which is variable and dependent upon the amount of force.

Does that describe Ersek?

A. No, it does not. Ersek describes a device which is to replace the surgeon's sutures. On his expanded

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device it only increases the diameter of two points. It does not create the diameter of the whole length. It does not go to a second diameter. If anything, it would make it rather barrel-shaped or a rather complicated shape along the end and it is opened up by potentially a single stroke of this device. It is not controllable. It is put in, bang, stapled in place.

Q. Now, last element. Next element. Whereby the tubular member may be expanded and deformed to rcpsnfd the lumen of the body passageway.

Does that describe Ersek?

A. Ersek is not taught and is not used to rcpsnfd the lumen. It is used to join something together. It is used to replace the surgeon's sutures. There is no teaching in Ersek of expanding the lumen, of using it to treat an area of narrowing.

Q. And, lastly, must be smooth in the first diameter.

Does that describe Ersek?

A. No. Ersek is the antithesis of smooth. Ersek has a multitude of outwardly projecting edges. As Ersek teaches in the patent. That cannot be fairly characterized as smooth.

Q. Now, in his opening statement, Mr. Badenoch made some comments about a declaration submitted to the Patent Office by doctor George Andros.

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Were you here for the opening when he made those comments?
A. Yes.
Q. Are you familiar with the declaration of Dr. Andros?
A. Yes, I am.
Q. I'd like you to take a look at it. It's PX-4042, which I offer.
MR. BADENOCH: No objection.
BY MR. DISKANT:
Q. Who's Dr. Andros?
A. He's a vascular surgeon who was familiar with both techniques used in vascular surgery and also interestingly had used balloon catheters, and he wrote a declaration used by the Patent Office in one of the re-examinations to explain what Ersek was and what Ersek wasn't.
Q. And did he make points similar to the ones you've made this afternoon?
A. Yes. In broad terms, he made exactly the same points that I've been making this afternoon.
Q. Okay. Let's take a look at some excerpts from Dr. Andros' declaration submitted to the U.S. Patent Office.
He says the Ersek patent discloses an invasive procedure which is the antithesis of the noninvasive procedure in the '762 patent. Involved an

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open surgical procedure.
Do you agree with that?
A. Absolutely. Ersek is related to the practice of surgery, to major open surgical procedures. It has nothing to do with intraluminal delivery.
Q. Let's see other slide.
There's no teaching or suggestion in the Ersek patent that the fixation sleeve could be used to dilate, rcpsnfd or scaffold an occluded or stenosed artery. A suture replacement device.
Do you agree with that?
A. Absolutely, I agree with it. Ersek is teaching you would put it into a transplant situs even if there was a stenosed or narrowed artery, you would take that out or replace it. Ersek is to join together two things. You would be putting in a replacement graft. Ersek has nothing to do with expanding an area of narrowing.
Q. Okay. Let's go to the next slide, please.
The fixation sleeve is performed to provide a multitude of narrow projecting edges that are intended to imbed themselves into the tissue wall upon expansion of the sleeve. These sharp metal projecting and penetrating edges are a fundamental requirement for the successful operation of the fixation sleeve. Thus, the

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periphery of the Ersek sleeve is rough, sharp, and not smooth.
Do you agree with that?
A. I do. These are the words in the patent, a multitude of narrow projecting edges and Dr. Andros characterizes these as being rough, sharp and certainly not smooth. And I agree entirely with that. That's a fair characterization of Ersek.
Q. Next slide, please.
It's clear from a comparison of the figures that the expansion tool therein is capable of expanding the fixation sleeve by a very limited amount.
Do you agree with that?
A. I agree completely with that.
Q. Let's see the next slide.
The term intraluminal delivery as it relates to the invention in the '762 patent is intended to mean, or is understood by those in the art to mean that the graft or prosthetic device is delivered a long distance from a remote location, through the lumen of a body passageway, without surgically exposing the desired location. The Ersek device cannot be intraluminally delivered as that term is understood by those skilled in the art.
Do you agree with that?

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A. I agree with that completely. Ersek is teaching a surgical procedure where you've opened the patient up, you're operating on them, you're removing parts, replacing parts. This has nothing to do with Dr. Palmaz's intraluminal delivery, which is a non-surgical atraumatic procedure.
Q. No responsible physician would consider intraluminally delivering the Ersek expanded metal fixation sleeve by catheterization through the vasculature of a lumen, since the outwardly projecting edges on the outer periphery thereof would present a clear risk to the patient.
Do you agree with that?
A. I agree with it completely. Ersek teaches a device, a sleeve, which matches the area you're teaching. He does not teach a first diameter small device. He teaches specifically something that matches the area you're treating. If you tried to force that, the sides of the area you're treating and the vessel, you would damage the vessel significantly, and he uses word to describe that, all of which I agree with.
Q. May we see the next slide, please?
Since the Ersek fixation sleeve is expanded, i.e., partially deployed, prior to insertion in the body passageway, any attempt to deliver the Ersek fixation

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1995.
Q. '85?
A. Sorry. 1985, a fuller count was published by both groups.
Q. Okay. And let's look at those. Palmaz is PX101 and Gianturco is PX-3093.
MR. DISKANT: And I offer both.
MR. BADENOCH: No objection.
THE COURT: Thank you.
DEPUTY CLERK: So marked.
*** (Plaintiff's Exhibits No. 101 and 3093 were received into evidence.)
BY MR. DISKANT:
Q. Let's first look at Palmaz's article in July1985 and this is in Radiology. What's Radiology?
A. Radiology is a scientific medical journal published by the RSNA. It's the published journal which corresponds to the meeting that you looked at the program abstract.
Q. So now we're in July and Radiology publishes Dr. Palmaz's article.
Let's just pull up the footnote, make sure what this is based on. Presented at the 70th Scientific Assembly, RSNA, November 25 to 30, 1984.
So what's that telling you about the content

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of this article?
A. This is a paper now which is related to the contents of what Dr. Palmaz presented at the meeting.
Q. Okay. And does he reveal in the article he used an angioplasty balloon to controllably expand the stent?
A. Yes.
Q. The endo prosthesis is mounted on a modified angioplasty catheter. When the angioplasty balloon is dilated in the stenosed vessel, the wire mesh expands, talking about his woven wire mesh design now?
A. Yes. He's talking about the wire mesh design.
Q. The wire mesh expanded with the balloon and remains expanded and in place after the balloon is deflated and withdrawn.
Does that refer to controllable expansion?
A. Yes.
Q. And deformation?
A. Yes. This is plastic deformation, bending of the structure.
Q. Use of a balloon to expand a prosthesis?
A. Yes. An angioplasty catheter is a balloon catheter.
Q. Okay.
A. It specifically says angioplasty balloon.
Q. So this is the idea of the balloon expandable

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stent?
A. Yes. In brief form, this is the -- this is the idea of the balloon expandable stent.
Q. Is it yet the idea for the slotted tube balloon expandable stent?
A. No. This is the woven wire mesh, which does not have smooth, doesn't have uniform or thickness because it has strut over strut, so many place all over it.
Q. Now, did the editors of Radiology recognize that Gianturco's self-expanding stent was a competing idea with Dr. Palmaz's balloon expandable stent?
A. Yes, they did, and this article down in the subscript actually references Dr. Gianturco's work and his article so that the reader of this article could cross-reference and read about Dr. Gianturco's competing spring uncontrollable stent.
Q. It says see also the article by Wright, et al. Was that the Gianturco group?
A. Yes.
Q. Pages 69 to 72 in this issue.
A. Yes.
Q. What is that telling the interested reader in improving the results of angioplasty?
A. It's highlighting the fact that two competing ideas, that's Dr. Palmaz's controllably plastically

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deformed balloon expandable stent and there's Gianturco and Kenneth Wright's spring device.
Q. Okay. Now, Gianturco is published in the same issue. It's PX-3093. Let's see that.
It's write, Gianturco and others. Let's just pull up the footnote and see what this article is based on.
This also is presented at the 70th meeting, November 25 through 30, 1984.
So is this article also based on the presentations that Dr. Gianturco and his group made in that November '84 meeting?
A. That's correct.
Q. And do the editors of Radiology tell the interested reader about Palmaz?
A. Yes. At the bottom of this, you will see they say, see also article by Palmaz, et al., and they give their page numbers so you can have a look and see this competing idea. The plastically deformable controllable stent or the spring pop-open device.
Q. Now, is there another annual meeting of the RSNA the following fall?
A. Yes. There's one each year. The RSNA, including this year, has an annual meeting each year, and there was one the following year.